PATENT QUALITY IMPROVEMENT: POST-GRANT OPPOSITION

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

JUNE 24, 2004

Serial No. 91

Printed for the use of the Committee on the Judiciary

Available via the World Wide Web: http://www.house.gov/judiciary

U.S. GOVERNMENT PRINTING OFFICE

94–459 PDF WASHINGTON : 2004

For sale by the Superintendent of Documents, U.S. Government Printing Office
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THURSDAY, JUNE 24, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, THE INTERNET,
AND INTELLECTUAL PROPERTY,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to other business, at 4:23 p.m., in Room 2141, Rayburn House Office Building, Hon. Lamar Smith (Chair of the Subcommittee) presiding.

Mr. SMITH. We will now proceed to an oversight hearing on patent quality improvement: post-grant opposition, and our witnesses are welcome to come forward and take their seats. I am going to recognize myself for an opening statement and then will recognize Mr. Boucher for his.

A year ago to this day, our Subcommittee conducted a hearing on patent quality improvement by examining six reform proposals. Today's hearing on post-grant opposition is the next stop on the Subcommittee's patent reform tour. Passage of the patent fee bill, H.R. 1561, consumed much of this Subcommittee's time earlier this term. The Patent and Trademark Office desperately needs the additional revenue.

While H.R. 1561 doubtlessly will improve PTO's administrative ability to tackle the problems of application pendency and backlogs, these goals should not supersede the need to improve public confidence in the validity of issued patents. All roads should lead to enhanced patent quality. Patents of dubious probity only invite legal challenges that divert money and other resources from more productive purposes, purposes such as raising venture capital, commercializing inventions and creating jobs.

Today's hearing addresses an important subject that could strengthen how parties challenge the scope and validity of weak patents. The primary administrative procedure for addressing such disputes in the United States is reexamination, which may be initiated by any party during the life of the patent. Conceived in 1980, reexamination permits the patent owner or any other party to request that the PTO reconsider the grounds on which the patent was originally issued. Initiation of a reexamination requires that some previously undisclosed new and relevant piece of prior art be presented to the agency.

The standard, a substantial new question of patentability, prevents the reopening of issues deemed settled in the original examination. A relevant disclosure must also be printed in either a prior

patent or prior publication. No other source can serve as grounds for the reexamination. A major criticism of this system is that its ex parte nature limits the participation of third parties. In response, our Subcommittee developed an inter partes component of reexamination in 1999 and amended the provision further in the 107th Congress to encourage its use.

Unfortunately, the proceeding remains something of a white elephant to most challengers, in part because they are estopped under its terms from asserting claims in later court proceedings that could have been raised during reexamination.

A more elaborate and adversarial procedure for challenging the validity of patents in the immediate aftermath of their issuance is the European opposition proceeding. This system permits challengers to contest a wider range of issues related to patentability in a more robust, almost trial-like, manner. Unlike reexamination, however, European post-grant claims must be made within 9 months of a patent's issuance.

While our witnesses and many inventors may embrace post-grant in the abstract, the patent community at large has not coalesced around the particulars of one proposal. The purpose of this hearing, therefore, is to explore whether the adoption of a post-grant system in the United States would improve patent quality. If so, what will be the prominent features of the new construct?

Whatever our initial differences today, I hope that next year, we will draft legislation that enhances, perhaps by replacing, the current reexamination process. Our goal is to empower inventors to challenge the scope and validity of patents when truly appropriate in an administrative setting.

That concludes my opening statement, and the gentleman from Virginia, Mr. Boucher, is recognized for his.

Mr. BOUCHER. Mr. Chairman, thank you very much for convening today's hearing on ways to improve the process by which patents are awarded. I would like to say a word of welcome to our witnesses today who represent a very diverse group of interests, and we are very glad to have you here.

Under current law, it is very difficult to challenge a patent once it has been awarded, even if there is evidence of the existence of prior art or other matters that would render the patent invalid. The current inter partes reexamination process is limited to prior art. Other matters may not be raised in such a proceeding. If someone initiates an inter partes reexam, he is confronted with the application of the estoppel principle in any later court proceeding with respect to the matters he raised in the inter partes reexamination proceeding, and any matters he could have raised are also subject to estoppel in a later court process.

No cross-examination of witnesses is permitted in the inter partes reexamination; no oral testimony is permitted during the inter partes reexamination, and so, it really is a process on paper where material is submitted, limited just to the question of whether or not there is prior art. No argument is permitted essentially on either side.

And so, not surprisingly, given the limited nature of this process, it is no wonder that the application of estoppel at the end of it ren-

ders the process all but useless, and in fact, it has not been used a great number of times.

If the party wanting to contest a patent decides to go to court, he is also confronted with a very high hurdle, and that very high hurdle is a clear and convincing evidence standard. That is a barrier that is difficult to surmount, and so, under current law, when you look at all the various processes open, you have to conclude that it is extraordinarily difficult to challenge a patent.

I personally believe that patent quality would be enhanced if we had a more meaningful process through which these claims can be raised. The current system clearly can be improved, and I would suggest, as others have, that the creation of a postaward opposition offers a meaningful opportunity to challenge patents before going to court. That approach has merit, and I am pleased to see a consensus developing, as I think will be represented by our witnesses here today, that a meaningful postaward opposition proceeding would be a positive step for us to implement.

There are some other issues that our witnesses may care to address, and let me simply list these: first of all, should we consider a provision that would require the publication of all patent applications after 18 months? Under current law, the only patent applications that must be published after 18 months are those that are destined for international filing as well as for domestic filing. And those that are for domestic filing only escape the current 18-month publication. So one question is should we expand to all patent applications, including those that are domestic only, the 18-month filing requirement?

There are political problems associated with that that I readily acknowledge, but I would be interested in learning from our witnesses whether they think in theory it is a good idea. In the case of submarine patents, should the law be changed to remove the automatic injunction that now applies against the defendant whenever the court finds that an infringement has occurred when one of these submarine patents arises, and instead, perhaps, a provision would be better if it required the court to weigh the harms to both sides in such an instance before deciding whether or not to issue an injunction.

A third possible question is at what point should a person be able to file a declaratory judgment action for a judgment on the validity of a patent held by someone else? Is it upon the receipt of a licensing letter from the patent holder? Is it upon the threat of suit against the person who may be involved, perhaps, in a manufacturing application by the patent holder? Or should it be upon the occurrence of some other event that we determine that a case in controversy exists and therefore make eligible a declaratory judgment action?

These are just some of the questions that I think revolve around the very important subject of steps we could take here in order to improve patent quality, and I again want to commend the Chairman for his strong interest in this subject, for convening today's hearing and also thank the witnesses for their participation.

Mr. SMITH. Thank you, Mr. Boucher. Without objection, other Members' opening statements will be made a part of the record.

And let me proceed to introduce our witnesses. Our first witness is Jim Toupin, who became general counsel for the U.S. Patent and Trademark Office in January 2001. In that capacity, Mr. Toupin provides legal advice and court representation for the PTO and conducts oversight of the PTO Office of the Solicitor, Board of Patent Appeals and Interferences and Trademark Trial and Appeal Board.

Mr. Toupin was educated at the Boalt Hall School of Law at Berkeley, where he served as editor of the California Law Review and at Stanford, where he received a bachelor's degree in history Phi Beta Kappa. He has published widely on various intellectual property, health and trade issues.

Our next witness is Jeffrey Kushan, a partner and patent attorney at Sidley, Austin, Brown & Wood's Washington, D.C. office. He is testifying on behalf of the biotechnology company Genentech. Last year, American Lawyer Magazine named Mr. Kushan as one of the top 45 lawyers in the United States under the age of 45. Mr. Kushan, I remember asking you about that before. When are you going to age out? [Laughter.]

Five more years? And do they have a top 50 under 50? [Laughter.]

Just a 45 under 45; okay.

In any case, he is very distinguished. He serves as Chairman of the American Bar Association's Patent Law Committee and as an adjunct faculty member of the George Washington University. Mr. Kushan is a graduate of the George Washington University Law School. He earned a master's in chemistry from the University of North Carolina at Chapel Hill and a bachelor's in chemistry from the College of William and Mary.

Our next witness is Mike Kirk, the executive director of the American Intellectual Property Law Association. Before joining AIPLA, Mr. Kirk worked at the Patent and Trademark Office for nearly 30 years. Mr. Kirk earned his bachelor of science in electrical engineering at the Citadel in 1959; his juris doctor in 1965 from Georgetown Law Center; and his master of public administration in 1969 from Indiana University.

Our final witness is Mr. Karl Sun, who became Google's first patent counsel in 2002. Prior to joining Google, Mr. Sun practiced law in California and counseled emerging corporations on development finance and intellectual property matters. He has also clerked for the Federal Circuit. Mr. Sun studied electrical engineering, computer science and technology and policy at MIT, where he earned a bachelor of science and two master of science degrees. He completed his legal studies at Harvard and served as editor of the law review.

Welcome to you all, probably the most educated witnesses we have had in a long time before the Subcommittee, and we appreciate your taking the time and giving us your expert advice. We have statements from all of our witnesses, and without objection, they, too, will be made a part of the record.

We would ask you to keep your testimony, if you could, to 5 minutes, and with that, we will proceed, and Mr. Toupin, would you start?

TESTIMONY OF JAMES A. TOUPIN, GENERAL COUNSEL, U.S. PATENT AND TRADEMARK OFFICE (PTO), WASHINGTON, DC

Mr. TOUPIN. Good afternoon, Chairman Smith, Congressman Boucher, Members of the Subcommittee. I am pleased to have this opportunity to present the U.S. Patent and Trademark Office's views regarding post-grant review of patents. Before I turn to this important subject, I want to take a moment to thank you for your continued leadership on innovation and USPTO issues.

As you know, the Office's 21st Century Strategic Plan was developed in response to a Congressional requirement. This blueprint for modernizing the office contains 37 initiatives that focus on quality, productivity and e-Government. Creating a new procedure to permit the agency to review economically significant patents after they are granted based on full participation of interested parties is an important part of the strategic plan's emphasis on patent quality.

Over the past 25 years, Congress has incrementally added to the USPTO's jurisdiction under which third parties could seek office review of issued patents. In 1980, Congress introduced ex parte reexamination, under which a third party could petition for reexamination of a patent. In 1984, section 135 of the Patent Act was amended to allow issues of patentability as well as priority to be included in interference proceedings, and in 1999, Congress, as part of the American Inventors Protection Act, created inter partes reexamination, whereby a third party could participate in a reexamination proceeding. That, as the Chairman mentioned, was amended in 2002.

The USPTO's ability to review issued patents has grown. But none of these procedures have fully utilized the Office's ability to review issued patents. For example, interference proceedings only lead to challenges of patents when a pending application raises a priority issue as to a recently-issued patent. Further, except in interferences, a third party cannot conduct discovery and develop evidence necessary to challenge patentability, nor can a third party challenge patent owner evidence by cross-examination.

More typically, a third party may only challenge the patentability of patent claims in the Office based on certain prior art references, namely patents or printed publications, by reexamination. However, potential challengers have regarded ex parte reexamination as an insufficient mechanism because after the proceeding has begun, the third party's participation is limited at most to one reply.

The inter partes reexamination procedure was intended to address this defect; however, limitations on that process, as noted, have led it to be rarely used. Only 46 inter partes reexaminations have been instituted during the nearly 5 years for which the procedure has been available.

This history helped the USPTO develop its strategic plan and consider whether it could improve its capability to conduct post-grant review. The USPTO proposes a review model different from reexamination, namely, a genuinely contested case presided over by a panel of administrative patent judges which, upon the challenger's presenting sufficient grounds to believe that patent claims are unpatentable, would include closely-directed discovery and cross-examination.

The proceeding would be designed to be concluded within a year and would provide for challenges based on all grounds of unpatentability but not inequitable conduct. They would be available to challengers for a year after a patent issues and thereafter to those threatened with patent infringement litigation.

The USPTO's proposal is thus designed to put review of the propriety of patent claims that the public regards as important in the hands of senior, legally-qualified officials with experience in dispute resolution. It is designed to be more efficient than litigation while preserving enough of the full participation according to parties in litigation that challengers will be able to risk being able to be bound by the result. By providing for the possibility of amendment of challenge claims, the proposed system would preserve the merited benefits of patent claims better than the win-all-or-lose-all validity contests in District Court.

The subsequent response from those studying the patent system and from user groups suggests that post-grant review is an idea whose time has come. As you may know, two recent reports on the U.S. patent system issued since the 21st Century Strategic Plan espoused post-grant review proposals strikingly similar to the USPTO's. Interested groups such as AIPLA and the Intellectual Property Owners have also passed resolutions supporting the concept.

It is time to develop a new American procedure that will increase public confidence in one of America's truly great legacies, the patent system, by establishing a comprehensive post-grant review of patent validity. We contemplate that it will be a cost-effective alternative to litigation while strongly protecting the public and respecting the inventors who are at the heart of the system.

We look forward to working with the Subcommittee and interested parties to develop a sound proposal that will draw on the capabilities of the USPTO to better serve the vitality of the patent system.

Thank you.

[The prepared statement of Mr. Toupin follows:]

PREPARED STATEMENT OF JAMES A. TOUPIN

Statement of

James A. Toupin

General Counsel
United States Patent and Trademark Office

before the

SUBCOMMITTEE ON COURTS, THE INTERNET AND INTELLECTUAL PROPERTY
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES

on

June 24, 2004

Good Afternoon Chairman Smith, Ranking Member Berman, and Members of the Subcommittee, I am pleased to have this opportunity to present the U.S. Patent and Trademark Office's (USPTO) views regarding the Post-Grant Review of patents.

Before I turn to this important subject, I just want to take a moment to thank you all for your continued leadership on innovation and USPTO issues, in particular your leadership on one of our legislative priorities the "USPTO Fee Modernization Act," H.R. 1561. While the House-passed bill has some differences from the Administration's proposal, the House has taken a vital step in enhancing the role that intellectual property plays in promoting the growth of the American economy. This crucial step would not have been possible without your leadership and support.

As you all know, the "Fee Bill" is necessary to implement our 21st Century Strategic Plan. The Strategic Plan was developed in response to a congressional requirement.[1] Accordingly, the Strategic Plan was created after a rigorous top-to-bottom

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[1] See 21st Century Department Of Justice Appropriations Authorization Act, Pub. L. No. 107-273, § 13104, 116 STAT. 1758 (Nov. 2, 2002).

review of all USPTO operations, policies, and procedures. This resulting blueprint for modernizing the Office contains 37 initiatives that focus on quality, productivity, and e-government. As former Under Secretary James Rogan testified before this Subcommittee in the past, patent quality is one of the most important, if not the foremost, goals of the agency.[2] Creating a new procedure to permit the agency to review economically significant patents after they are granted based on the full participation of interested parties is an important part of the Strategic Plan's goal to enhance patent quality.

I. History and Background of Post-Grant Review

As the Members of the Subcommittee know, the USPTO confers property rights in the form of a patent grant to applicants who meet the criteria established by Congress and pursuant to applicable case law. These patentability criteria for an invention are set forth in Title 35 of the United States Code and include eligibility/utility (§ 101), novelty (§ 102), non-obviousness (§ 103), and the written description and enablement of the invention and definiteness of the claims (§ 112).

Currently, the USPTO has only a limited role in reconsidering patentability decisions after patents issue. The post-grant review of patent claims takes place before the USPTO under several circumstances, including,

(1) when a patentee files an application to reissue a patent to correct at least one error in the patent,
(2) when an applicant and a patentee claim the same invention and an interference is declared between the patentee and the applicant, and the applicant seeks judgment based on unpatentability of patent claims, and
(3) when a patent owner or third-party requests the reexamination of a patent.

Congress has incrementally added to the range of proceedings under the USPTO's jurisdiction under which third parties could provoke Office review of issued patents. It introduced *ex parte* reexamination in 1980, under which a third party could petition for reexamination of the patent.[3] In 1984, section 135 of the Patent Act was amended to allow issues of patentability, as well as priority, to be included in interference proceedings.[4] In 1999, Congress, as part of the landmark patent reform, the American Inventors' Protection Act (AIPA), created *inter partes* reexamination, whereby the third party could participate in the reexamination proceeding and appeal to the USPTO's administrative Board of Patent Appeals and Interferences.[5] The AIPA's *Inter Partes*

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[2] See *"United States Patent and Trademark Modernization Act of 2003" Hearing before the Subcomm. on Courts, the Internet and Intellectual Property*, 108th Cong. 61 (2003) (Statement of James E. Rogan, Director, United States Patent and Trademark Office).
[3] Pub. L. No. 96-517, § 1, 94 Stat. 3016 (1980).
[4] Pub. L. No. 98-622, 98 Stat 33831 (1984).
[5] Intellectual Property and Communications Omnibus Reform Act of 1999, S. 1948, Pub. L. No. 106-113 (1999).

reexamination practice was expanded in 2002 to afford third parties the right to appeal to the U.S. Court of Appeals for the Federal Circuit.[6]

Although through these amendments, the USPTO's role in helping guarantee the efficacy of the patent system after patent issuance has grown, none of these procedures alone, or collectively, have proven sufficient to optimize the USPTO's post-grant capability. Although a patentability challenge can be raised on all grounds in interferences, interference proceedings only lead to challenges of patents when a pending application raises a priority issue as to a recently issued patent. Further, a third party may file a protest in a reissue proceeding; however, that is rare, and the third party has very limited participation. Apart from interferences and a reissue protest, a third party may challenge the patentability of patent claims in the Office only based on certain prior art references, namely patents or printed publications via reexamination. In addition, except in interferences, a third party cannot conduct discovery and develop evidence necessary to challenge patentability, nor can the third party challenge patent owner evidence by cross-examination.

Potential challengers have also regarded *ex parte* reexamination as an insufficient mechanism because, after the proceeding has begun, the third party's participation is limited to one reply, and then, only if the patent owner files a pre-examination statement. As a result *ex parte* reexamination has not been utilized by third parties to the degree anticipated. The *inter partes* reexamination procedure established in 1999 was intended to address this defect; however, limitations on that process have led to it being rarely used. In particular, patentees understandably insisted, and Congress legislated, that a challenger in an *inter partes* proceeding be bound by its result by way of estoppel, including in subsequent litigation. However, the lack of such procedural mechanisms as discovery and cross-examination that would be available in litigation appears to mean that challengers have been unwilling to invoke *inter partes* reexamination and risk its estoppel effect. In fiscal year 2003, for example, the USPTO received approximately 355,000 patent applications and issued approximately 160,000 patents. Over the past five years, we have received approximately 1,600,000 applications and issued approximately 900,000 patents.[7] Yet, the total requests for *inter partes* reexamination during the nearly five years for which the procedure has been available, is a mere 46 .[8]

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[6] *21st Century Department of Justice Appropriations Authorization Act*, Pub. L. No. 107-273, 116 Stat. 1758, 1899-1906 § 13202 (2002).

[7] U.S. PATENT AND TRADEMARK OFFICE PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2003. http://www.uspto.gov/web/offices/com/annual/2003/index.html.

[8] These *inter partes* reexamination requests included 29 patents from mechanical technologies, 8 in electrical arts, 7 in chemical arts, and 2 in biotechnology.

II. Alternatives for Reform: Establishing a New Post-Grant Review System

This history helped lead the USPTO in developing its Strategic Plan and considering whether it could improve its capability to conduct post-grant review of issued patents. The goals of any post-grant review process are as important today and should be the same goals as when Congress considered this issue more than twenty-years ago. Then, the reexamination process was being pioneered by former Subcommittee Chairman Robert Kastenmeier, who during floor consideration of the legislation, summarized its goals:

> First, to settle validity disputes more quickly and less expensively than litigation;
> Second, to allow courts to refer patent validity questions to an agency with expertise in both the patent law and technology; and
> Third, to reinforce investor confidence in the certainty of patent rights by affording an opportunity to review patents of doubtful validity.[9]

The current system, we concluded, has turned out to be too limited in a variety of substantive and procedural ways to meet these objectives.

Accordingly, we looked to the experiences of interferences and reexamination to see if the USPTO could suggest an alternative that would come closer to satisfying these objectives. The result was a post-grant review proposal published on the USPTO web site in April of 2003 as part of its 21st Century Strategic Plan.[10] It proposes a review model different from reexamination -- namely, a genuinely contested case presided over by a panel of administrative patent judges, which, upon the challenger's presenting sufficient grounds to believe that patent claims are unpatentable, would include closely directed discovery and cross-examination. The proceeding would be designed to be concluded within a year and would provide for challenges based on all grounds of unpatentability, but not inequitable conduct. It would be available to all challengers for a year after a patent issues and thereafter to those threatened with infringement litigation.

The USPTO's proposal is thus designed to put review of the propriety of patent claims that the public regards as important in the hands of senior, legally qualified officials with experience in dispute resolution. It is designed to be more efficient than litigation, while preserving enough of the full participation accorded to parties in litigation that challengers will be willing to risk being bound by the result. By providing for the possibility of amendment of challenged claims, the proposed system would preserve the merited benefits of patent claims better than the win-all or lose-all validity contests in district court.

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[9] 126 Cong. Rec. 29, 895 (1980) (Statement of Rep. Kastenmeier). See also H.R. Rep. No. 96-1307 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460; see *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 601; 225 U.S.P.Q. (BNA) 243, 248 (Fed. Cir. 1985).

[10] See *Action Papers and Implementation Plans as of April 2, 2003, Post-Grant Review of Patent Claims*, located at http://www.uspto.gov/web/offices/com/strat21/action/sr2.htm.

This procedure may be reminiscent of legislation introduced by Representatives Berman and Boucher last session, the "Patent Improvement Act of 2001," H.R. 1333. In fact, many of the ideas that the USPTO is incorporating are not new, but rather in accord with much of that legislation to create some sort of post-grant review of issued patents. Many of the concepts that are proposed regarding "post-grant" have been discussed in various circles for decades, including among members of the stakeholder and bar communities. It is necessary to emphasize that we are not creating the "opposition panel" that is detailed in H.R. 1333; however, we are confident that the Subcommittee will be pleased by how far our proposal goes while being respectful of the independent inventor and the small business community. In fact, the small business community will be the greatest beneficiaries of this reform.

The subsequent response from those studying the patent system and from user groups suggests that such a more robust post-grant review procedure is an idea whose time has come. As you may know, two recent reports on the U.S. patent system issued since the 21st Century Plan, espouse post-grant review proposals strikingly similar to the USPTO's. Interested groups such as the American Intellectual Property Law Association and the Intellectual Property Owners also passed resolutions supporting the concept.

This is not to say that all those who have spoken on the issue have espoused exactly the contours of the proposal that the USPTO put forth in its Strategic Plan. For example, in February, the Office conducted a roundtable discussion where we heard from more than a dozen members of the public, the bar, and the inventor community on post-grant procedures. Some participants, particularly those representing small companies, suggested that the USPTO's proposal did not go far enough – that a post-grant review proceeding should be more fully available throughout the life of the patent, so that potential new entrants could test the validity of patents before they begin research and development efforts. Conversely, other participants would limit the time in which such a challenge could be brought in the Office.[11] Yet the participants advocated the desirability of a more rigorous means for testing patent claims. Further, there was general agreement that it was desirable to provide a post-grant system that is more predictable, timely, and reliable than exists today.

The experience of the past twenty-five years helps establish what such a system must avoid. Such a system:

- must *not* be a system that allows for the harassment of inventors and patent owners. We intend to have a rigorous standard for allowing full proceedings and sanctions for frivolous filings. Inventors should not be faced with re-litigating issues that there has been an opportunity to air thoroughly before the USPTO.

- must *not* be a Japanese or European-style opposition system which has been criticized as being wide open-ended and indeterminate procedures for the parties

[11]The statements for this event are available at *Roundtable on Equities of Inter Partes Re-examination Proceedings* held Feb 17, 2004 and documented at http://www.uspto.gov/web/offices/pac/dapp/opla/comments/reexamproceed/news_and_notice.htm.

involved. Our proposal includes tightly controlled time frames. We will have definite scope and durations.

Drawing, however, on the lessons of the past twenty-five years, we believe it is time to develop a new American procedure that will help increase public confidence in one of America's truly great legacies – the Patent System – by establishing a more rational post-grant inquiry regarding patent validity. We contemplate that it will be a cost-effective alternative to the acknowledged litigation crisis while still strongly protecting the public and respecting the inventors at the heart of our system.

We look forward to working with this Subcommittee and interested parties to develop a sound proposal that will draw on the capabilities of the USPTO to better serve the vitality of the patent system.

I know that there is great interest in this subject and I look forward to answering your questions. Thank you.

Mr. SMITH. Thank you, Mr. Toupin.
Mr. Kushan?

TESTIMONY OF JEFFREY P. KUSHAN, ESQUIRE, SIDLEY AUSTIN BROWN & WOOD, ON BEHALF OF GENENTECH, INC.

Mr. KUSHAN. Thank you, Mr. Chairman. I want to congratulate you, Mr. Boucher and the other Members of the Subcommittee for taking up this important issue and, as you noted, I am here on behalf of Genentech today. Genentech very much appreciates the opportunity to provide its views on this important topic for legislation.

Genentech is one of the world's leading biotech companies. It was formed just over 25 years ago, which, if you do your math, makes it the first biotech company. It is based in South San Francisco, California. Genentech is an active user of the patent system and owns thousands of patents. Genentech depends on the security of those patents to protect its cutting edge products, and securing effective patent rights is instrumental to Genentech's ability to bring new products to the market for the benefit of patients.

Genentech commends the Subcommittee for taking up this issue for deliberation and for legislative action. We strongly support the Committee's efforts to design and implement an effective administrative post-grant review procedure and to do so rapidly.

As other witnesses have and will observe, there is a broad support within and outside of the patent community for creating an effective administrative procedure for reviewing the validity of an issued patent. We believe this reflects an appreciation that the existing procedures are not effective, not balanced and not fair. It also demonstrates a clear need for an option other than patent litigation in a Federal court to resolve questions that may exist regarding the validity of a patent.

The challenge for Congress, however, is to devise a system that not only provides a rigorous inquiry into the validity of the patent but is also structured to prevent harassment of the owners of valid patents. A system that allows frivolous challenges to be made or which can be used to tie up a patent in a long and endless administrative proceeding would fail to meet the needs of those users of the patents community and the needs of the public.

Similarly, a process which is as complex, burdensome and expensive as patent litigation would yield few benefits. The broad support you see for creating a new post-grant review procedure is based on an appreciation that the PTO does have a special expertise in certain matters relating to the validity of a patent. Specifically, PTO can use professionals with a scientific or technical expertise in the field of the invention. The PTO is also intimately familiar with the application of certain of the patentability requirements: novelty, nonobviousness, written description, enablement and utility.

Genentech is confident that Congress can devise an appropriately-structured administrative procedure rather than attempt to go into every parameter you might see in that system which might take 5 minutes or, at this point, two and a half minutes, we would like to emphasize a few critical parts of the system, whatever its shape, from Genentech's perspective.

First, it is very important that the procedure permit review of compliance with the written description and enablement requirements of 35 USC 112 and the utility requirement of 35 USC 101. These requirements ensure that a patent applicant is entitled to the breadth of the patent rights that have been awarded and that the patent owner has possession of the invention when the patent application was filed.

The utility requirement ensures that the patent owner has identified credible, specific and substantial utility for the claimed invention. These factors presently dominate the examination of biotechnology patent applications and are often important factors in evaluating the validity of many biotechnology patents. A post-grant review system that does not permit review of these issues would fall far short of its potential.

Second, any party wishing to commence a proceeding should be required to establish that one or more claims in the patent are prima facie invalid. If the PTO finds, through its independent assessment, that that proof is not sufficient, then it should not start a proceeding. This threshold determination, in our view, is extremely important to protect the interests of patent owners and should not be omitted from any system.

Third, we believe Congress should not attempt to create any special statutory estoppel provisions in any new system. These estoppel provisions that we have seen in the inter partes regime have really deterred use of that regime. I would note that we do not see that there is any need for any special statutory estoppel provision in litigation. The issues that you fought about in front of the Patent Office will be vibrantly pointed out by your opponent, and there is a natural estoppel that attaches that a court is going to give deference to, so we see no need for any special construct that would expand that estoppel provision.

Fourth, and this is a point which I do not believe has picked up a lot of attention in the past, we do not believe that the proceedings that you conduct after the patent is issued should give rise to a basis for holding the patent unenforceable under the inequitable conduct doctrine. Under existing law, a patent can be held unenforceable by showing that a patent applicant during the ex parte examination of the application engaged in inequitable conduct before the Patent Office.

A special duty of disclosure is imposed on the patent applicant to make sure that the public interests are protected. That is because the public cannot participate in that ex parte examination. Unfortunately, the issue of inequitable conduct is a virtual plague in patent litigation today in creating new grounds for letting that arise in litigation; it would be very unhelpful.

And finally, we believe that it would be very useful to have a fixed period during which oppositions can be commenced. We are open to considering options where it would be possible to commence an opposition after that time period has ended.

In conclusion, we just thank you for the opportunity to give you our views.

[The prepared statement of Mr. Kushan follows:]

PREPARED STATEMENT OF JEFFREY P. KUSHAN

Mr. Chairman and distinguished Members of the Subcommittee,

My name is Jeff Kushan. I am a partner in the Washington office of the law firm of Sidley Austin Brown and Wood, LLP. I am also a registered patent attorney, and specialize in the areas of biotechnology, pharmaceuticals and software-related inventions.

Today, I have the privilege of offering testimony on behalf of Genentech, Inc. Genentech is a world-leading biotechnology company, based in South San Francisco, California. Genentech is committed to developing new biotechnology products to meet unmet medical needs. Genentech actively procures patent protection for its technology, and depends on an effective and fair patent system. Genentech very much appreciates the opportunity to provide testimony to the Subcommittee on the issue of today's hearing. We commend you, Chairman Smith, along with your colleagues on the Subcommittee, particularly the Ranking Member, Mr. Berman, for taking up this important and timely issue.

Genentech strongly supports the creation of an effective, fair and expeditious post-grant administrative patent review procedure. Options that exist today—so-called *ex parte* and *inter partes* reexamination—do not present a viable alternative to litigation in the Federal courts, primarily because these procedures do not provide third parties with a fair and balanced degree of participation relative to patent owners. The absence of a fair and efficient administrative procedure to review patent validity makes it possible for owners of invalid patents to use the often enormous expense of patent litigation to shield invalid patents from challenge. An improperly granted patent that cannot be reviewed in a cost-effective manner creates unjustified burdens and risks for American companies, including those in the biotechnology industry.

Genentech believes that the availability of an appropriately structured post-grant review system will enhance public confidence in the patent system, and provide the public with a much needed administrative alternative for resolving questions of patent validity. We recognize that there is broad support within and outside the patent community for creating a viable post-grant patent validity review procedure. The challenge, however, will be for Congress to define certain critically important elements of such a procedure—in this case, the devil truly is in the details. Our testimony below identifies what we believe to be the most significant requirements of a viable post-grant review procedure. We thank the Subcommittee for giving us the opportunity to share our views on this important issue, and stand ready to work with the Congress to make a viable post-grant patent review procedure a reality.

INTRODUCTION

The United States patent system is structured to deliver reliable results in a cost-effective and timely manner. Examination is conducted on an *"ex parte"* basis—meaning that the PTO and the patent applicant are the only participants in the examination process. The advent of publication of patent applications prior to grant from the 1999 American Inventors Protection Act (AIPA) has shed some light onto ongoing examinations, but, fundamentally, the patent examination process remains closed to substantive participation by parties other than the patent applicant.

Practical considerations mandate that this model continue. The PTO, given its resource constraints, simply cannot administer a system that permits third parties to intervene in the examination of pending applications. Experiences in other countries that do permit intervention in the examination of applications are uniformly negative. These experiences show that in many instances, third parties intervene to simply delay the issuance of a patent, which disrupts business expectations of patent applicants and consumes limited patent office resources. Allowing public intervention in the examination of pending U.S. applications would create immense practical problems, given the volume of applications now pending before the PTO, and the limited amount of examination resources that are available.

The logical alternative is a *post*-grant review procedure administered by the PTO. Congress, perhaps recognizing this, has always focused on procedures that envision an opportunity for the public to have the PTO review the validity of an issued patent. The first such system adopted by Congress was the *"ex parte"* reexamination system, enacted in 1982. In the *ex parte* reexamination system, any person, including the patent owner, may commence a reexamination of any issued patent on the basis of a patent or a printed publication that raises a substantial new question of patentability. See, 35 U.S.C. § 302. The *ex parte* reexamination procedure, like original examination, is a closed procedure—only the patent owner and the PTO participate substantively in the proceeding. As a result, most third parties avoid use of

this procedure for commercially significant patents, since it does not afford those third parties a meaningful opportunity to participate in the proceeding.

THE 1999 *INTER PARTES* REEXAMINATION EFFORT

In 1999, Congress created an enhanced version of reexamination, termed *"inter partes"* reexamination. The *inter partes* reexamination procedure does provide more of an opportunity for third parties to participate in the proceeding. However, due to the limitations built into the system, this "enhanced" version of reexamination has fallen short of expectations. The limited number of *inter partes* reexamination requests that have been commenced—despite the fact that hundreds of thousands of otherwise eligible patents have issued since enactment of the legislation—suggests that the design of this procedure will continue to limit its use by the members of the public.

The most significant deficiencies of the *inter partes* reexamination system can be summarized as follows.

- It is not possible to use the procedure to review patentability issues that are most commonly encountered in biotechnology patents and applications; namely, compliance with 35 U.S.C. §§ 101, and 112, first paragraph. It has been our experience that issues of compliance with the written description and enablement provisions of 35 U.S.C. § 112, first paragraph, and the utility requirement of § 101, frequently are significant inquiries affecting the validity of many biotechnology patents and patent applications. Not permitting these grounds to be raised in a post-grant review procedure renders the system far inferior as an alternative to litigation in a Federal court.
- The law imposes two distinct "statutory estoppels" that in combination make the procedure unattractive as an alternative to litigation in a Federal court. The first, found in 35 U.S.C. § 315(c), prohibits a requestor from raising in a Federal court *any* issues of validity that "could have been raised" at the time of the request for reexamination in view of art known to the requestor. This broad estoppel attaches by the mere filing of a *request* for *inter partes* reexamination. The second "estoppel" is found in an uncodified section of the AIPA (§ 4607 of the Intellectual Property and Communications Omnibus Reform Act of 1999, as enacted by § 1000(a)(9) of Public Law 106–113), and is designed to prohibit a third party who participates in a reexamination proceeding from later contesting the legitimacy of any "facts" determined in the proceeding. These statutory estoppel provisions impose an unacceptable price on use of the *inter partes* reexamination procedure in almost all situations.
- The *inter partes* reexamination system does not permit third parties to use certain evidentiary procedures that would ensure that the procedure is sufficiently rigorous. For example, it is not possible to cross-examine expert witnesses used in the proceeding or direct questions to the opposing party.
- Finally, the system cannot be used to review issues of validity involving patents issued on applications filed before November 29, 1999. We note that this limitation, in particular, has rendered the system of marginal value to many companies in the biotechnology industry, in part because there still remains a significant number of biotechnology patent applications pending before the PTO that were filed before this date.

These limitations in the *inter partes* reexamination system—ostensibly established in 1999 to provide a more robust alternative to *ex parte* reexamination—have made the procedure of marginal value to the public. It is not an effective alternative to expensive, unpredictable and protracted litigation in the Federal courts. As such, the *inter partes* reexamination procedure has not met expectations.

RECENT DEVELOPMENTS

In the past year, the Federal Trade Commission (FTC) and the National Academies of Science (NAS), have both issued reports calling for the creation of a more robust and effective administrative post-grant patent review system. The motivation for these organizations is the same as that which led Congress to establish the *ex parte* and *inter partes* reexamination procedures. Specifically, each organization recognizes that the PTO has a special expertise in evaluating certain patentability issues, such as anticipation, nonobviousness, enablement, written description and utility. They also recognize that certain issues often addressed in litigation before a Federal court (e.g., infringement, inequitable conduct) are a major source of the high cost of patent litigation, yet are not pertinent to validity of the patent. Both organizations accurately recognize that an administrative patent validity review proceeding can be conducted more rapidly than litigation in a Federal court, and

that the public would significantly benefit from the availability of a procedure that does not present the burden, duration and associated expenses of patent litigation. These organizations also appreciate that that any new system should not permit third parties to harass patent owners, or initiate groundless attacks on patents.

RECOMMENDATIONS FOR REFORM

Genentech believes it is possible to create a viable, cost-effective, and fairly balanced post-grant administrative patent review procedure. A variety of models have been proposed for such a system in the past few years, including those from the Patent and Trademark Office in its 21st Century Strategic Plan, the NAS, the FTC and the American Intellectual Property Law Association (AIPLA). Many of these proposals have significant merit, and could serve as a suitable foundation for legislation. Moreover, these organizations have identified a number of important assumptions and conditions for a successful post-grant review procedure. We encourage the Congress to study these proposals carefully.

The excellent work done by these organizations also permits us to focus on a number of key issues that Genentech believes are of particular importance, regardless of the ultimate framework chosen for the system. We note that each of these organizations, for example, recognize that the PTO has resource constraints. They also recognize that the PTO has a special expertise in certain, but not all patentability issues. For example, the PTO rarely encounters issues associated with compliance with the "best mode" requirement of 35 U.S.C. § 112, first paragraph. Similarly, the PTO does not often evaluate compliance with the duty of disclosure requirement of 37 CFR § 1.56. Such topics in which the PTO has no special expertise or which cannot be fairly evaluated using objective inquiries should not be placed in the hands of the PTO to evaluate in a post-grant review procedure.

We also recognize that certain decisions will have to be taken as to how the new regime relates to the existing *ex parte* and *inter partes* reexamination procedures. For example, we believe there is value in retaining an efficient and simple documentary procedure for reviewing validity issues raised by a patent or a printed publication. It may be possible to design a flexible post-grant review procedure to permit parties to conduct the procedure in a way that preserves this "least complicated" approach. We also believe it is appropriate for the PTO to continue to have the authority to conduct Director-ordered reviews, but to expand this authority to evaluate compliance with issues under 35 U.S.C § 101 or § 112, first paragraph (other than best mode).

The Congress should also carefully evaluate how multiple proceedings initiated under the new system will be coordinated, both with respect to other opposition requests, and with interference proceedings. We note that it may be desirable to provide statutory guidance to the PTO and to parties as to how such proceedings may be merged, suspended or otherwise coordinated so as to reduce the potential burdens on patent owners involved in multiple proceedings, and to ensure that efficient disposition of validity issues associated with a patent.

With these initial observations in mind, we believe there are a number of important parameters that must be included in any post-grant review procedure. These can be summarized as follows:

1. *Scope:* The system must permit review of questions of compliance with 35 U.S.C. § 101 and § 112, first paragraph (other than best mode), in addition to §§ 102 and 103. As noted earlier, compliance with the written description and enablement requirements of 35 U.S.C. § 112, first paragraph, and with the utility requirement of § 101, is often an important inquiry for a biotechnology patent. These issues also tend to be among the more significant issues addressed during original examination, rather than prior art issues. A system that omits the possibility of raising these non-prior art issues would significantly reduce the value of a post-grant review procedure to most biotechnology companies.
2. *Estoppel.* Participation in a post-grant review system must not create any barrier for the participants to litigate patent validity on issues that were not actually raised and addressed in the post-grant review proceeding before the PTO. Genentech believes Congress should avoid including estoppel provisions in any post grant review legislation, and should specifically avoid including provisions that are comparable to the codified and uncodified estoppel provisions applicable to *inter partes* reexamination proceedings.
3. *Preliminary Showing to Initiate Procedure*—Any party wishing to commence a proceeding should be required to set forth, supported by substantial evidence, a prima facie showing of invalidity of one or more claims. If such an

initial showing is not made, the Office should not commence the proceeding. Genentech believes this "initial proof" requirement is an important part of any post-grant review procedure that could result in invalidation of one or more claims of a patent. Without this initial determination, patent owners could be subjected to groundless challenges to their patents.

4. *Time Limits to Initiate Proceeding.* Any third party should be allowed to initiate a post-grant review proceeding provided it has made an appropriate preliminary showing within a fixed period following issuance of the patent. In our view, that period of time could range from one to two years after grant of the patent. Genentech also believes it may be appropriate to allow post-grant review proceedings to be commenced after this fixed period has expired, but only in strictly limited circumstances. One example would be where the patent owner consents to having the proceeding commenced before the PTO. Genentech remains open to consideration of additional, appropriately limited circumstances in which oppositions may be commenced after a fixed period from patent grant.
5. *Applicable to All Patents.* The system should permit review of any patent that is capable of being enforced, subject to the threshold showings and limitations noted above. Thus, the system should permit review of patents issuing on applications filed on or before the effective date of the American Inventors Protection Act.
6. *Limited Additional Evidentiary Procedures.* Genentech believes a viable post-grant review procedure should permit use of evidentiary procedures that will provide a more rigorous review of issues pertinent to the validity of a patent than are permitted under the current *inter partes* reexamination authority. At the same time, we recognize that if all the evidentiary procedures available in litigation before a Federal Court were allowed to be used in a post-grant review procedure before the PTO, no benefits would be realized from using the PTO-based procedure. As a result, Genentech believes it would be appropriate to make available only certain limited additional procedures in a post-grant review procedure. Such additional procedures should include the right to cross-examine a witness who offers testimony in the proceeding. Additionally, if the presiding authority (e.g., an administrative patent judge) finds it appropriate, certain additional procedures could be made available including: (i) limited requests for admissions, (ii) a limited number of interrogatories, and (iii) the opportunity for an oral hearing. Other measures, however, should be prohibited. In particular, parties to a post-grant proceeding should not be subject to document production, or forced to produce fact witnesses for depositions. Such restrictions are appropriate and will not undermine the effectiveness of the procedure, in part because they are unnecessary. We note in this regard that the PTO, unlike a court, can use officials with technical expertise in the particular field of a patented invention to conduct and manage proceedings. This provides the PTO with a capacity to independently assess assertions made by the parties to the proceeding. We believe these limitations on the types of evidentiary measures made available in a post-grant proceeding will help to ensure that the PTO procedure does not replicate the functions of full-scale litigation in a Federal court.
7. *Prohibit inequitable conduct challenges based on actions of parties during post-grant proceedings.* The inequitable conduct doctrine operates to ensure that patent applicants during *ex parte* examination of their applications are held to a higher standard of dealing with the PTO. See, 37 CFR § 1.56. A party that does not meet his or her duty of disclosure to the Office can cause that party's patent to be held unenforceable. The reason for this enhanced duty of disclosure is that the *ex parte* examination procedure is closed and the public cannot participate. Unlike *ex parte* examination, however, post-grant review procedures under consideration would be public and would include the active participation of one or more parties opposed to the patent owner. These factors eliminate the need for any enhanced disclosure standards comparable those imposed during original examination. Moreover, there is no comparable sanction that can be imposed on third parties in such a proceeding (i.e., those parties will be free to litigate infringement, enforcement and invalidity in the future largely unfettered by their participation in the proceeding). In view of this, Genentech does not believe it would be appropriate to impose an enhanced duty of disclosure on participants in a post-grant proceeding that could result in the patent being held unenforceable. Certainly, regulations designed to ensure proper conduct of parties in such proceedings are appropriate, and should be enforced by the PTO. If the PTO

finds that one party has made a misrepresentation, it should have the authority to take actions to sanction that party during the proceeding. Where such misrepresentations are discovered after the patent emerges from the proceeding, courts may give due consideration to the actions of the party, but should not be allowed to hold the patent unenforceable.

8. *Authority to Delegate Certain Issues for Resolution.* The PTO faces annual challenges and uncertainty in its funding. In view of this, it would be desirable for Congress to allow the PTO to delegate responsibility to private parties to resolve certain fact issues. For example, as is the case with the existing interference authority, the PTO may allow parties to arbitrate certain issues. In a similar fashion, the PTO could allow a third party to adjudicate certain conflicts, and then to rely on those findings in making its patentability determinations. This authority may be useful to have to ensure that funding problems do not adversely affect the progress of cases that have been commenced. Genentech believes, however, that the ultimate determination of validity of the patent within the context of these proceedings—once a proceeding has been commenced—must remain the exclusive jurisdiction of the PTO. In other words, while we support the use of appropriate cost-saving measures, the PTO must continue to make its final, independent determination of whether a patent meets the statutory requirements of validity.

CONCLUSIONS

Genentech relies extensively on the patent system to protect its innovations. Our experiences teach us that invalid patents cause the greatest business disruptions—both when Genentech owns the patent and when Genentech is facing the patent. A cost-effective procedure that allows for robust participation by third parties, yet is appropriately limited to avoid prejudice and the problems of litigation before a Federal court, would provide immense value for patent owners and the public alike.

As Congress begins it deliberations on this important issue, it should keep certain fundamental principles in mind. First, there is no right of a member of the public to retain and enforce an invalid patent. It also is not appropriate to permit entities to use the high cost and complexity of patent litigation to prevent discovery of invalidity of a patent. Invalid patents impose an immense and unjustified cost on American businesses, including companies in the biotechnology industry.

Second, we believe a properly designed system must incorporate safeguards to ensure that it will not be abused by third parties. As noted above, the devil is in the details. The challenge is for Congress to create a procedure that provides a rigorous and balanced inquiry into the validity of a patent, and to make that procedure feasible for the PTO to administer. A system that permits a third party to paralyze a patent by initiating an open-ended administrative proceeding would seriously undermine the incentives and purpose of our patent system. Likewise, a proceeding that becomes comparable in complexity, burden and cost to litigation in the Federal courts would yield no benefits.

Finally, a patent review system administered by the PTO must remain focused on those issues that the PTO has special expertise in evaluating, and work within the practical constraints of an administrative proceeding that is designed to be efficient but thorough. In particular, the system should avoid having the PTO evaluate questions of compliance with the "best mode" requirement of 35 U.S.C. § 112, or compliance with the duty of disclosure under 37 CFR § 1.56. The system should also build on the recognition that the PTO can bring a special technical expertise to independently evaluate scientific and technical questions that bear on patentability. At the same time, the PTO is not well-equipped to manage contentious proceedings that will turn on critical evidentiary questions. As such, we encourage the Congress to incorporate safeguards that take account of these limitations, and to not create a system that the PTO is incapable of effectively managing.

Genentech thanks the subcommittee for the opportunity to present its views, and encourages the Congress to act promptly to enact this much-needed legislation.

ATTACHMENT

Genentech
IN BUSINESS FOR LIFE

BACKGROUNDER

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http://www.gene.com

GENENTECH

Genentech's mission is to be the leading biotechnology company, using human genetic information to discover, develop, manufacture and commercialize biotherapeutics that address significant unmet medical needs. We commit ourselves to high standards of integrity in contributing to the best interests of patients, the medical profession, our employees and our communities, and to seeking significant returns to our stockholders, based on the continual pursuit of scientific and operational excellence. The company has headquarters in South San Francisco and is traded on the New York Stock Exchange under the symbol DNA.

Eighteen of the currently approved products in biotechnology originated from or are based on Genentech science. Genentech manufactures and commercializes 12 products in the United States:

- Herceptin® (Trastuzumab) for first line therapy in combination with paclitaxel and as a single agent in second and third line therapy for patients with metastatic breast cancer who have tumors that overexpress the HER2 (human epidermal growth factor receptor2) protein;
- Rituxan® (Rituximab) for the treatment of patients with relapsed or refractory low-grade or follicular, CD20 positive, B-cell non-Hodgkin's lymphoma;
- Avastin™ (bevacizumab) for use in combination with 5-Fluorourcil-based chemotherapy in the treatment of first-line metastatic cancer of the colon or rectum;
- Xolair® (Omalizumab) for Subcutaneous Use for the treatment of moderate-to-severe persistent asthma in adults and adolescents;
- RAPTIVA™ (efalizumab) for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy;
- TNKase™ (Tenecteplase), a single-dose clot-busting agent for the treatment of acute myocardial infarction (heart attack);
- Activase® (Alteplase, recombinant), a tissue-plasminogen activator to dissolve blood clots, for treating patients with acute myocardial infarction, patients with acute massive pulmonary embolism (blood clots in the lungs), and for treating patients with acute ischemic stroke (brain attack) within the first three hours of symptom onset;

- Cathflo™ Activase® (Alteplase), athrombolytic agent for the restoration of function to central venous access devices as assessed by the ability to withdraw blood;
- Nutropin AQ® [somatropin (rDNA origin) injection], a liquid formulation of Nutropin for the same indications as Nutropin®;
    - Nutropin AQ Pen™ for use with Nutropin AQ Pen™ Cartridge, a delivery device for Nutropin AQ® [somatropin (rDNA origin) injection] that provides simplicity, convenience, and safety features;
- Nutropin® [somatropin (rDNA origin) for injection] human growth hormone for treating GHD, for treating growth failure due to chronic renal insufficiency prior to kidney transplantation, and for treating short stature associated with Turner syndrome;
- Protropin® (somatrem for injection) growth hormone also for the treatment of GHD in children;
- Pulmozyme® (dornase alfa, recombinant) Inhalation Solution, the first new therapeutic approach for cystic fibrosis in more than 30 years.

Medicine Development at Genentech

Genentech has the biotechnology industry's most extensive track record in all phases of bringing new disease treatments to patients – from discovery research through development, commercialization and product operations. With 12 protein-based products on the market for serious or life-threatening medical conditions, Genentech has experience taking a drug from A to Z, transforming the seed of an idea in a lab into a novel therapy for a patient in need. Such a fully integrated approach differentiates Genentech from other biotechnology companies.

Discovery Research

Research is the wellspring of potential products, and Genentech's research organization is among the world's finest. Genentech scientists are the most prolific in the biotechnology industry, publishing at a rate of 200+ scientific papers a year, and are among the top researchers in the world in terms of total citations. In addition, Genentech's scientists have secured more than 4,600 patents worldwide and have another 5,000 pending.

Discovery research at Genentech focuses primarily on three areas of medicine where there is a strong need for safer, more efficacious therapies: oncology, immunological disease, and disorders of tissue growth and repair, with a major focus on angiogenic disorders. In addition, Genentech remains open to other projects where the company has significant opportunities to fill a therapeutic void in important areas of medicine.

To ensure continued scientific excellence, Genentech opened the Founders Research Center, a 275,000 square-foot, $85 million research facility devoted solely to biotechnology, in October 1992. It was dedicated to Bob Swanson and Dr. Herbert Boyer in honor of their pursuit

of the promise of biotechnology when they established Genentech 25 years ago in 1976. In April 2001, the company celebrated its 25th anniversary by breaking ground on the 280,000 square foot expansion of the Founders Research Center. Completed in 2003, the complex – comprising the existing facility and the new expansion – houses specialized laboratories and state-of-the-science equipment in several interconnected buildings.

Development

Genentech uses a rigorous set of criteria, including scientific factors, medical need and market potential, to determine which projects to move from discovery research into development. The scientists and medical professionals in Laboratory and Clinical Development then play the essential role of translating basic science into patient benefit. They help Genentech determine which potential new drugs are tested against specific diseases in the clinic and guide chosen drug candidates through the many phases of clinical testing. Therapeutic proteins must be delivered into the body safely, and their effectiveness must be measured and documented in order to secure marketing approval. Genentech's development pipeline has both breadth and depth, with projects targeting a range of disease areas across all phases of clinical development.

Manufacturing

Genentech was the first biotechnology company to scale up protein manufacturing successfully from the small quantities used for research to the much larger quantities needed for clinical trials and marketing. With approximately 30 percent of the world's total licensed capacity for the production of biologics, Genentech is the world leader in biologics manufacturing. Over the last two decades, Genentech has built world-class production facilities, developed expertise in commercially viable manufacturing processes and also attracted and retained key personnel with experience in all aspects of large-scale biologics manufacturing. Genentech's manufacturing expertise and capacity (more than 275,000 liters of installed fermentation capacity) provide important competitive advantages in the maturing biotechnology industry and position the company well to meet the demands of its promising product pipeline. Genentech presently has two manufacturing facilities in California (South San Francisco and Vacaville) and one nearing completion in Porriño, Spain.

Commercialization

Commercial translates research and development innovations into changes in medical practice that enhance and extend patients' lives. The Commercial team introduces multiple products into new and different markets, directs pre-launch commercial development activities, and utilizes cutting-edge sales approaches. The Commercial organization is also involved with development activities that bring forward products in the pipeline in the most efficient way to meet the demands of the market and the healthcare community – directing market research, sponsoring medical education efforts, and developing a leading patient reimbursement program. The Commercial team's unique consultative education, sales, marketing, and distribution models have resulted in 13 successfully marketed products to date and have made Genentech a valuable and sought-after partner.

Product Pipeline

With close to $3 billion in cash and investments and 2003 revenues of more than $3.3 billion, Genentech reinvested approximately 22 percent of its revenues into research and development (R&D) in 2003 — significantly more than the pharmaceutical industry average. To balance resource use with the strongest likelihood of success, Genentech moves only the most promising of its products into clinical development.

Genentech's development pipeline continues to grow, now numbering over 30 projects in three therapeutic focus areas – oncology, immunological disease, and vascular medicine – with an additional category for projects outside of these focus areas, specialty therapeutics. The pipeline is also balanced between breakthrough innovations and new indications for existing, well-understood products that may fight more than one disease or more than one form of a disease.

Oncology

Genentech is taking part in the fight against cancer by continuously studying and developing therapies for a variety of cancers, including four of the most common – lung, breast, prostate, and colon. At present, we are investigating Avastin and Omnitarg™ (Pertuzumab) in multiple tumor types; Tarceva™ (erlotinib HCl) in non-small cell lung cancer, pancreatic cancer, and brain cancer; and our marketed products Herceptin and Rituxan in several new oncology indications.

Immunology

Immune disorders such as asthma, psoriasis and rheumatoid arthritis affect over 20% of the population of the United States. Immunology is a growing area of expertise and emphasis for Genentech, and we are developing several potential therapies for immune-related diseases. Our two most recently approved products, RAPTIVA for moderate-to-severe chronic plaque psoriasis and Xolair for moderate-to-severe persistent asthma, are aimed at immunological conditions.

Vascular Medicine

An example of our investigational work in vascular medicine is our anti-angiogenesis drug, Lucentis™ (ranibizumab), formerly rhuFab V2, which is being studied for the potential treatment of age-related macular degeneration.

Specialty Therapeutics

Genentech also develops medicines outside of these three focus areas, provided they address unmet medical needs and utilize the company's areas of expertise. Our medicine for cystic fibrosis, Pulmozyme® (dornase alfa), and our growth hormone products are in this category.

Employees

Genentech's success is predicated on its ability to recruit and retain highly qualified and motivated people in all areas of the company. Of the more than 6,200 Genentech employees, more than 80 percent have college degrees and more than 20 percent hold advanced degrees, including Ph.D.s and M.D.s. Genentech demands the best from its employees and rewards them accordingly with a benefits plan that includes healthcare benefits that are among the best in the industry, an employee stock purchase plan, a paid sabbatical program and a large corporate-sponsored child care center.

Access to Care Foundation

Although Genentech's products are covered by most government and private insurance, Genentech has established the Genentech® Access to Care Foundation to make its marketed products available to qualified uninsured or underinsured patients in the United States. In 2003, more than 4,200 patients participated in the program and Genentech provided more than $40

million worth of drugs to patients in need, keeping the company's promise that no one will go without a Genentech product based on financial reasons alone.

Corporate Growth Strategy

Genentech aims to continuously create growth in different areas of the company. With this in mind, Genentech developed the "5X5 goals" in 1999, five goals it plans to meet by year-end 2005. These goals help the company stay focused on its top priorities and make Genentech's plans transparent to investors and others:

- 25% average annual increase in EPS
- 25% net income as % of revenues
- 5 new products/indications approved
- 5 significant products in late stage clinical trials
- $500 million in new revenues from strategic alliances or acquisitions.

Genentech's performance against these ambitious goals remains strong.

Genentech has also turned its attention to the period beyond 2005 and developed a long-term company strategy, Horizon 2010, that builds on the success of our 5X5 goals and covers the period from 2006 to 2010. Because research and development can take many years, we are investing now to achieve the kind of revenue and earnings growth needed to remain a leading company past 2005. Horizon 2010 includes the following elements:

Our Vision

Utilize the science of biotechnology to become the world leader in revolutionizing the treatment of patients with cancer, immunological diseases and angiogenic disorders.

Our Goals

- Strive to become number one in U.S. oncology sales by 2010.
- Position ourselves for continued leadership in oncology by bringing five new oncology products/ indications into clinical development and into the market.
- Build a leading immunology franchise by expanding the fundamental understanding of immune disorders, by bringing at least five new immunology products/indications into clinical development, and by obtaining approval of at least five new indications or products by 2010.
- Increase our leadership in developing biotherapeutics for disorders of tissue growth and repair, with a major focus on angiogenic disorders, and move at least three new projects into late-stage research or developmental research and three or more new projects into clinical development by 2010.

- Achieve average annual earnings per share (EPS) growth rates sufficient to be considered a growth company.

Our Strategy

- Manage the business with a primary intent of building sustainable, long-term growth in stockholder value

- Be recognized leaders in:
  - B-cell mediated diseases
  - Disorders of tissue growth and repair, particularly angiogenic disorders
  - Targeted therapies and their enabling diagnostics

- Excel in:
  - Making and shaping markets
  - Influencing the practice of medicine
  - Maximizing distinctive consultative selling approach
  - Manufacturing protein pharmaceuticals in a safe, high-quality, reliable, and cost-effective manner

- Scale our unique culture to remain a great place to work by:
  - Constantly emphasizing improving the lives of patients
  - Being the place for talented people to make a difference
  - Living our values
  - Sharing the financial success of the company with employees

# # #

June 2004

Mr. SMITH. Thank you, Mr. Kushan.
Mr. Kirk?

TESTIMONY OF MICHAEL K. KIRK, EXECUTIVE DIRECTOR, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION (AIPLA)

Mr. KIRK. Thank you, Mr. Chairman.

I am very pleased to have the opportunity to present the views of AIPLA on the question of improving patent quality with a post-grant opposition system. Any time patents are issued which appear to be of questionable validity, it undermines the confidence of businesses and consumers. While the validity of such patents may be tested through litigation, reexamination, reissue and interference, all of these options suffer significant deficiencies.

Litigation is expensive, averaging $1.5 million to $4 million per party, depending on the amount at risk. Both types of reexamination, as has been pointed out, also have failings. They are limited to patents and printed publications. In ex parte reexamination, the third party requestor is effectively denied any opportunity to participate. Inter partes reexamination, which was designed to allow and encourage that participation, has failed primarily due, as was pointed out, to the stringent estoppel provisions and also to the requirement to name the real party in interest. Reissues and interferences generally are not available to challengers and therefore play a minor role in that respect.

We agree with the PTO that the time is now for an effective post-grant opposition system. AIPLA has attempted, through the establishment of a blue ribbon committee back in November, to establish recommendations for a post-grant system, first by formulating a draft text of such a system to try to understand better what the problems would be when you get down to the details.

In a perfect world, we would have a post-grant opposition system in which every issue relevant to patentability could be raised and resolved quickly and inexpensively. All parties would have the opportunity to obtain discovery, present affidavits and declarations, present live testimony, cross-examine the opposing party's witnesses and generally conclude the proceeding rapidly, perhaps within 1 year.

In the real world in which we live, however, this is not possible. Compromises are inevitable. The proceeding must be sufficiently attractive that the public will be willing to use it. The grounds must be those which the PTO can effectively handle. All parties must have a reasonable opportunity to present evidence and to test the evidence presented by the other party. They must have confidence in the decision makers, and patentees must be protected against undue harassment and delay.

We believe that the proposal that we have developed accomplishes these goals in a fair and balanced manner. We would propose that the proceeding have the following attributes—first, a 9-month period in which to request an opposition to encourage the public to promptly challenge questionable patents—a requirement to identify the real party in interest, but allowing that name to be kept in confidence and disclosed only when required by issues of fairness. This avoids the need for requestors to identify themselves

as targets for potential litigation. The proceeding should be handled by a panel of administrative patent judges, not by patent examiners. The patentee should have one opportunity to amend claims, but these claims should not be enlarged. Discovery should be generally limited to the cross-examination of affiants, with exceptions in rare circumstances.

The requestor should have the burden of establishing facts by a preponderance of evidence that would result in a conclusion inconsistent with the patent's presumed validity. A patent owner could rebut this request with his own factual evidence and expert opinions. A 1-year limit for concluding the proceeding, extendable by 6 months, similar to the process that the International Trade Commission follows; an opportunity for an oral hearing should be present, with the filing of briefs, reconsideration and an appeal to the Court of Appeals for the Federal Circuit.

Determinations of validity raised by a requestor would be preclusive against that requestor in any subsequent proceeding. And finally, any requestor should be precluded from later filing a request for an inter partes reexamination.

The draft bill text appended to our written statement is the result of 6 months of focused efforts by our blue ribbon committee. We recognize that this is only the beginning. Achieving a fair balance between the competing objectives is challenging. New ideas and perspectives can always improve the outcome. We also believe that the success of any opposition procedure can only be proven in practice and that achieving a balance would require adjusting the post-grant procedure and its relationship to both types of reexamination and to the other procedures based on the experience achieved.

One cautionary note that we would add: any post-grant opposition system will be of limited value unless the necessary resources are dedicated to its implementation. Hiring a number of properly-trained and skilled individuals to handle post-grant oppositions, irrespective of the details of the proposal adopted, will be essential if the system is to achieve the results intended and desired.

We believe that our draft proposal for a post-grant opposition system represents a solid foundation on which to build an effective system. We thank you for the opportunity to address this issue and look forward to working with the Subcommittee in designing such a system.

Thank you.

[The prepared statement of Mr. Kirk follows:]

PREPARED STATEMENT OF MICHAEL K. KIRK

Mr. Chairman:

I am pleased to have the opportunity to present the views of the American Intellectual Property Law Association (AIPLA) on the question of improving patent quality, specifically by establishing a post-grant opposition system in order to create a quick, relatively inexpensive, and effective means of challenging patents of questionable validity.

AIPLA is a national bar association whose nearly 15,000 members are primarily lawyers in private and corporate practice, in government service, and in the academic community. The AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users

of patents, and have a keen interest in achieving an efficient and effective post-grant opposition system.

INTRODUCTION

AIPLA commends you, Mr. Chairman, for taking a fresh look at how patent procedures can be improved to strengthen the quality of U.S. patents and enhance the confidence of inventors, businesses, and the investment community in the patent system. Any time patents are issued which, on their face, appear to be of questionable validity, it reflects negatively on the patent system and undermines the confidence of business and consumers. While the validity of such patents may be tested through litigation or ex parte or inter partes reexamination, these proceedings all suffer substantial disadvantages.

Litigation is very expensive. AIPLA conducts an Economic Survey of our membership every two years to collect data on a number of aspects of the practice of intellectual property law. According to the most recent Economic Survey, the average cost of patent litigation, including the costs of discovery, ranges between $500,000 and $3,995,000 per party, depending on the amount at risk.

In addition, it is only possible to test a patent's validity through litigation if the patentee brings an infringement action against a competitor or provides the competitor with standing to bring a declaratory judgment action based on threats by the patentee. Thus, a competitor cannot challenge a patent in litigation before the competitor incurs the costs and risks of developing and marketing a product.

Even where litigation is available to test the validity of a patent, the recent National Academy of Sciences (NAS) report, A Patent System for the 21st Century, reported that such litigation typically does not occur until 7 to 10 years after the patent is issued and final decision is not reached for another 2 to 3 years. Until the litigation has been concluded, there is uncertainty in the marketplace and uncertainty in the technology as to the scope of the patent right.

Another method of challenging patents is through reexamination in the United States Patent and Trademark Office (PTO), either ex parte or inter partes. While a reexamination can be initiated by a competitor promptly after patent grant, both types of reexamination suffer significant deficiencies. Both types of reexamination are limited to challenges based on patents and printed publications and are decided by patent examiners rather than by Administrative Patent Judges (APJs).

Ex parte reexamination, as its name implies, involves only the patentee and the examiner after it is initiated. Thus, a third-party requestor is denied any meaningful participation, allowing the patentee the exclusive right to argue the case to the examiner and to appeal any decisions adverse to the patentee. Moreover, the PTO has not succeeded in handling ex parte reexamination proceedings with the "special dispatch" required by the statute; one witness at the recent PTO Roundtable Regarding Inter Partes Reexamination reported that, based on a limited review, he found that ex parte reexaminations that went to the Court of Appeals for the Federal Circuit (CAFC) took 9.5 years from filing until issuance of the reexamination certificate (see Wegner, Transcript from Round Table Meeting, *www.USPTO.GOV*)

Inter partes reexamination was conceived to provide a more balanced procedure for the public by permitting greater participation by third-party requestors, but limitations added during the legislative process destroyed that balance. For example, unlike ex parte reexamination, which applied to all patents in force on the date of its enactment, the inter partes reexamination procedure only applies to patents issued on applications filed on or after November 29, 1999.

Also, the name of the real party in interest has to be revealed upon requesting inter partes reexamination. This creates a chilling effect by requiring requestors to essentially identify themselves as litigation targets under the challenged patent. A further chilling effect arises from the stringent estoppel provisions that were added during the legislative process even though third-party requestors have no recourse to discovery to aid in presenting their cases.

THE TIME FOR POST-GRANT OPPOSITION HAS COME

In view of the absence of an effective and inexpensive means to challenge patents, AIPLA, the PTO, the Federal Trade Commission (FTC), the NAS, and, just last week, the Intellectual Property Law Section of the ABA have all put forth suggestions for post-grant opposition proceedings as a means of permitting a more meaningful, timely and cost-effective opportunity for the public to challenge patents that may be of questionable validity.

In 1996, AIPLA proposed the establishment of a post-grant opposition system to provide parties with an efficient, effective, and relatively inexpensive procedure to evaluate whether the claims of an issued patent are too broad or simply should not

have been issued at all. The PTO, as part of its 21st Century Strategic Plan released in 2002, called for the post-grant review of patents. Last October, the FTC, in its report entitled *"To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy,"* also recommended the establishment of an effective post-grant opposition system. Earlier this year, the NAS, in its report mentioned earlier, recommended the creation of an "Open Review procedure" to provide "more timely, lower cost, and more efficient review of granted patents" to replace the current reexamination procedures. The resolution adopted by the IPL Section of the ABA is generally supportive of a post-grant proceeding along the lines of the proposal AIPLA has developed. The call for an effective, efficient post-grant system to review patents has reached a crescendo. It is time to act.

AIPLA PROPOSAL FOR POST-GRANT OPPOSITION

In November 2003, AIPLA President Rick Nydegger created a Special Committee on Patent Legislative Strategies to focus on legislative changes that are desirable and achievable for the U.S. patent system. The Special Committee was co-chaired by two former AIPLA Presidents and included as members a former U.S. District Court judge, a former PTO Commissioner, five other AIPLA Past Presidents, and several other distinguished patent attorneys. Among the many topics reviewed by the Special Committee was post-grant review. Building on the earlier proposal of AIPLA and the more recent recommendations of the PTO, the FTC, and the NAS, the Special Committee developed what is believed to be an effective and carefully balanced post-grant opposition proposal. That proposal was approved by the AIPLA Board of Directors following additional deliberation during several meetings. The challenge is significant because, in the view of many, no country has truly achieved an optimal opposition system.

In a perfect world, one would desire a post-grant opposition system in which every issue relevant to patentability could be raised and resolved quickly and inexpensively. Both opposer and patentee would have the opportunity to obtain discovery, be able to present affidavits and declarations, present live testimony, cross-examine the opposing party's witnesses and affiants, conclude the proceeding in no more than twelve months, accomplish this inexpensively, and protect the patentee from harassment. In other words, we would have the equivalent of a district court trial, but quickly and inexpensively and in the PTO.

In the real world in which we live, however, this is not possible. In designing a post-grant opposition system, compromises are inevitable. We must seek the appropriate balance of procedures to accomplish the competing objectives, noted above, in a fair, effective, relatively inexpensive, and reasonably prompt review process.

The proceeding must be sufficiently attractive for the public—largely competitors of the patentee—so that they will be willing to request an opposition. The grounds for challenging patents must be those which the PTO can effectively handle. Both opposer and patentee must have reasonable access to procedures to present evidence in support of their case and to challenge that presented by the other party, but without the time-consuming, expensive discovery that accompanies patent infringement suits. And patentees, especially small business and independent inventors, must be protected against harassment from multiple sequential challenges, and against undue delay in resolving questions of patent scope and validity. We believe that the new proposal we have developed for a post-grant opposition proceeding addresses these competing goals in a fair and balanced manner.

The principal features of our proposal for a new post-grant opposition proceeding are the following:

- Nine-month post-issuance period in which to request the opposition.
- Requirement to identify the real party in interest, but allowing its name to be kept confidential in appropriate cases, until such time as justice and fairness require disclosure.
- "Front loading" of the requester's evidence supporting the opposition is required to expedite the proceedings.
- Opportunity for the patent owner to respond with evidence.
- Opportunity for the patent owner to amend the claims at least once.
- Discovery is normally limited to cross-examination of affiants, but could be extended if required in the interests of justice.
- Requester has the burden of proof by a preponderance of the evidence.
- One-year time limit, start to finish, but extendable to no more than 18 months in appropriate cases.

- Opportunity for oral hearing, filing briefs, reconsideration, and appeal to CAFC by all parties to the opposition.
- Bar to any later inter partes reexamination by the opposer and no concurrent reexamination proceeding until the opposition terminates
- Estoppel against unsuccessful requester as to the validity issues actually decided, but with exceptions for issues based on later availability of new material evidence regarding a legal or factual issue.

We believe that the draft post-grant opposition proposal appended to our statement accomplishes these goals. The Special Committee held numerous meetings, prepared, debated, and revised several drafts, all the while receiving constant guidance from the Board of Directors and the substantive Standing Committees of AIPLA. As we worked to develop the details of a post-grant opposition procedure, we continually discovered new issues, the resolution of which has made our proposal more effective and balanced. Indeed, the varied background of the participants—attorneys representing independent inventors, large and small businesses, and universities—contributed to this balance.

As previously noted, the present proposal has been approved by AIPLA's Board and we believe it is a commendable beginning. I say beginning because we recognize, based on our recent experience, that achieving a fair balance between the competing objectives of a well-designed post-grant opposition proceeding is challenging, and new ideas and perspectives can always improve the product. I also say beginning because the success of any opposition procedure only can be proven in practice, and achieving a fair balance may well require adjusting the procedure or its relationship to ex parte and inter partes reexamination based on experience. I would like to outline for the Subcommittee the major features of our proposal, which is attached as an Appendix.

Any person would be permitted to file a request for opposition to an issued patent. The opposition request must be made not later than nine months after the patent is granted. However, the patent owner may consent to the filing of a request at anytime during the life of the patent. The requester would be required to provide a complete disclosure of the basis for the opposition together with the request. Copies of any patents and printed publications relied upon must be provided. If the requester relies on factual evidence or expert opinions in support of the opposition, the requester must provide all such evidence and opinions in the form of affidavits or declarations at the time of filing the request.

As with inter partes reexamination, the real party in interest must be identified. However, recognizing that this could discourage the filing of an opposition by a party fearful of identifying itself as a target for an infringement action, a real party in interest can request that its identity be kept separate from the file of the opposition. In such cases, the identity of the opposer would be made available only to government agencies or to persons demonstrating good cause.

The need for protecting the identity of the opposer is balanced, however, by the interests of justice and fairness in certain circumstances. For example, under our proposal, a request cannot be made for keeping the identity of the real party in interest separate from the opposition file where the opposer relies upon factual evidence or expert opinions in the form of affidavits or declarations. The patentee must be able in such a situation to learn the opposer's identify in order to effectively cross-examine the opposer's affiants and declarants. Similarly, if an appeal is taken from a final decision of the PTO, the identity of the real party in interest must become part of the opposition file.

AIPLA's proposed opposition proceeding would allow a broader range of issues to be raised than the existing reexamination proceedings, but they would not be coextensive with the issues of patent validity that could be raised in the courts. The issues in the opposition proceeding would essentially be co-extensive with the issues that a patent examiner considers in deciding whether to permit an application for patent to issue as a patent. We would exclude certain issues because they depend upon the state of mind of the inventors and are not susceptible to resolution in such an administrative proceeding without the availability of extensive discovery that would render the proceeding excessively expensive and lengthy. These include issues such as "best mode" in section 112 and priority of invention in section 102(g). The proceeding would permit consideration of issues under section 101 (patentable subject matter), sections 102(a) (known or used by others) and (b) (public use or sale), section 112 (¶¶1 & 2—written description and enablement), section 251 (¶4—no broadened reissue claims) and double patenting (only one patent per invention).

An opposition would be instituted upon request unless the Director determined it lacked substantial merit. The Director would assign the opposition proceeding to a panel of three APJs. The decision on the opposition would be made upon the pros-

ecution record that was the basis for the grant of the patent and the additional submissions by the parties to the opposition proceeding.

The patent owner would be afforded the opportunity to make a complete response to the opposition request and to provide factual evidence and expert opinions in rebuttal to the submission presented by the requester. However, the patent owner would not be permitted to later make additional evidentiary submissions, as a matter of right, after making the initial response to the request.

A patent owner would have the right to amend the claims of the patent as a part of the patent owner's response to the opposition request. Any amended claim could not enlarge or broaden the subject matter claimed in the patent. Subsequent amendments could only be made upon a showing of good cause. Where an amended claim raises a new issue of patentability, the requester would be permitted to address that new issue.

As noted previously, we believe that significant limitations must be imposed on the discovery available during an opposition in order to constrain costs and avoid unduly protracted proceedings. Thus, the only form of discovery that we believe should be available to any party to an opposition, whether the requester or the patent owner, is the right to cross-examine a person providing factual evidence or expert opinions. Thus, a patent owner would be able to depose a requester's declarants and affiants, and a requester would be able to depose a patent owner's declarants and affiants. Only those persons whose affidavits or declarations were submitted as part of the opposer's or the patentee's submission could be cross-examined by way of deposition by the other party during the opposition proceeding.

Other than depositions of these declarants or affiants, additional discovery would only be permitted if the requesting party demonstrates that it is required in the interests of justice. One example of where this might apply is where cross-examination reveals the existence of evidence that rebuts the affidavits submitted by the requester. Discovery should be permitted in this situation so that the evidence could be obtained. Thus, discovery in an opposition proceeding should be available only to the extent that discovery is currently authorized in patent interferences pursuant to 37 C.F.R. § 1.687(c).

The Director would have discretion whether to accept or reject supplemental submissions. It is anticipated that the Director would administer this authority in a manner so as to balance fairness to the parties with the desirability of bringing the proceeding to a timely and prompt conclusion.

An oral hearing would be held if requested by a party to the opposition, or ordered by the three-judge panel. Whether or not a hearing takes place, the three-judge panel would have authority to require the filing of briefs before deciding the issues raised in the opposition request. We would expect that briefs would be routinely required and operate in the manner of a typical pre-trial brief.

The fact-finding would be done on a "preponderance of the evidence" standard. Since the opposition proceeding involves an issued United States patent, the presumption that the patent is valid remains in effect. Thus, the requester would have the initial burden of making arguments and establishing facts by a preponderance of the evidence that would result in a conclusion inconsistent with the patent's presumed validity. Unlike court proceedings, however, the determination of invalidity would be based on the "broadest reasonable construction" of the claim. This is the standard used to test the patentability of a claim during examination.

The final determination of the Director in an opposition proceeding would be based upon a written decision, including findings of facts and conclusions of law on the issues raised in each opposition request.

Any party adversely impacted by a decision should have the right to request reconsideration and modification of the decision, not less than two weeks from the date of the decision. Any party to an opposition proceeding dissatisfied with a final determination of the Director may appeal to the CAFC.

A very important aspect of any post-grant-opposition proceeding is the effect the decision will have on the parties. If the estoppel provision is too harsh, no one will use the procedure, as we have seen with inter partes reexamination. If it is too lenient, patentees may be subject to needless repetitive challenges by the same party. Therefore, we believe that a determination with respect to any issue of validity actually raised by an opposer should be preclusive against that opposer in any subsequent proceeding, absent any factual evidence that could not have been reasonably discovered or presented. Given the relatively short, nine-month period for initiating an opposition and the limited discovery available to the parties, we believe this would strike the right balance.

We believe it is extremely important that an opposition proceeding terminate with a final determination within one year after institution. This one-year period would serve the public interest by providing prompt final determinations of patentability

issues raised in the opposition. Recognizing that exceptional circumstances could arise, however, we believe that any party to an opposition should be able to obtain an extension of the one-year period for no more than an additional six months upon a showing of good cause. In addition, the three-judge panel could *sua sponte* extend the period for six months.

We would provide, as with interference proceedings, that an opposition proceeding could be terminated upon the joint request of the opposer and the patentee. Any agreement or understanding between the patent owner and an opposer would have to be in writing and the opposition would not be terminated until a copy was filed in the Office. The request would have to be filed before the panel issued a written decision. Where an opposition is terminated, there would be no estoppel as to that opposer. If requested, the agreement would be kept separate from the file of the opposition, and made available only to Government agencies on written request, or to any person upon a showing of good cause.

Similar to reexaminations, any claim determined to be patentable would be subject to the intervening rights provision specified in the second paragraph of section 252 for claims in reissued patents.

The opportunity to bring an opposition proceeding is intended to encourage members of the public to make prompt submissions of facts and expert opinions bearing on the validity of U.S. patents. The proceeding, therefore, is designed to provide greater certainty to both inventors and the public on the scope of valid patent rights. To ensure against harassment by a requester, no patent for which an opposition has been instituted should later be the subject of an inter partes reexamination request by the party that initiated the opposition. However, this would not apply to parties who did not initiate an opposition.

The public should be able to continue to request ex parte reexamination based upon patents and printed publications for the life of a patent. This balance would best serve the public interest by granting members of the public administrative redress where questions of patentability exist for which additional consideration by the Office is desired, and in granting inventors finality in the administrative consideration of questions of patentability.

In addition, we would give the opposition proceedings preference over reexamination proceedings. Thus, reexamination requests filed by third parties during the nine-month period would be considered to be requests for an opposition. Once an opposition is instituted, however, later requests for reexamination would be stayed until the opposition is terminated.

A WORD OF CAUTION

The adoption of any post-grant opposition system by the United States would be of limited value unless the necessary resources are dedicated to its implementation. As a point of reference, the latest statistical report of the European Patent Office (EPO) indicates that the EPO granted 59,992 European patents in 2003. That same year, 2,634 patents, or approximately 4.4%, were opposed. In the context of the PTO which granted 189,597 patents in 2003, this would translate into over 8,000 oppositions. Even discounting this number by 90% to account for patent owners or others who would continue to use ex parte reexamination to test patent validity and who would be reluctant to use the post-grant opposition procedure, one could still be looking at a potential caseload that is many times the number of interferences currently handled by the Board. While interferences are admittedly more complex than the proposed post-grant oppositions, the adoption of a post-grant opposition system would require a significant increase in the number of APJs (20 of the 61 APJs currently at the Board are exclusively dedicated to interferences). Hiring the number of properly trained and skilled individuals needed to handle post-grant oppositions—irrespective of which proposal is adopted—will be essential if the system is to achieve the results intended. We cannot overlook this need when considering this change to the patent system.

CONCLUSION

AIPLA reiterates its support for an efficient, cost-effective post-grant opposition proceeding to serve as an alternative to litigation for challenging patents of questionable quality. Such a system must be comprehensive and balance a number of significant factors, providing an attractive option for third parties while avoiding harassment of patent owners. We believe that our draft proposal for a post-grant opposition system represents a solid foundation on which to build just such a post-grant opposition system. We thank the Subcommittee for its time and attention to

this issue and look forward to working with the Subcommittee in the design and implementation of such a system.

APPENDIX

Chapter 32—Post-Grant Opposition Procedures

Sec.

§ 321. Right to oppose patent; opposition request

(a) A person may request that the grant or reissue of a patent be reconsidered by the Office by filing an opposition seeking to invalidate one or more claims in the patent. The Director shall establish, by regulation, fees to be paid by the opposer. Copies of patents and printed publications to be relied upon in support of the request must be filed with the request. If an opposer relies on other factual evidence or on expert opinions in support of the opposition, such evidence and opinions must be filed with the request through one or more accompanying affidavits or declarations.

(b) Copies of any documents filed pursuant to subsection (a) must be provided to the patent owner or, if applicable, the designated representative of the patent owner, at the time of filing under subsection (a), except that if a request is made that the identity of a real party in interest be kept separate pursuant to section 322(b), then the identity of the real party in interest may be redacted from the copies provided.

(c) The file of any opposition proceeding shall be made available to the public except as provided in section 322.

§ 322. Real party in interest

(a) The person making the request shall identify in writing each real party in interest and the opposition shall proceed in the name of the real party in interest.

(b) If requested, the identity of a real party in interest shall be kept separate from the file of the opposition and made available only to Government agencies on written request, or to any person upon a showing of good cause. In the event that the identity of a real party in interest is kept separate from the file pursuant to this subsection, then the opposition shall proceed in the name of the individual filing the request as representative of the real party in interest. However, no request under this subsection to keep the identity of a real party in interest separate from the file of the opposition may be made or maintained if the opposer relies upon factual evidence or expert opinions in the form of affidavits or declarations during the opposition proceeding or if the opposer exercises the right to appeal under section 141.

§ 323. Timing of opposition request

An opposition request made under section 321 must be made not later than nine months after the grant of the patent or issuance of a reissue patent, except that, if the patent owner consents in writing, an opposition request may be filed anytime during the period of enforceability of the patent. A court having jurisdiction over an

issue of validity of a patent may not require the patent owner to consent to such a request.

§ 324. Limits on scope of validity issues raised

The opposition request must identify with particularity the claims that are alleged to be invalid and, as to each claim, one or more issues of invalidity on which the opposition is based. The issues of invalidity that may be considered during the opposition proceeding are double patenting and any of the requirements for patentability set forth in sections 101, 102, 103, 112 or 251, fourth paragraph, of this title, except for:

(a) the requirement in section 112, first paragraph, to disclose the best mode; and

(b) issues arising under section 102(c), 102(f), or 102(g).

§ 325. Institution of the opposition proceeding

(a) If one or more requests meeting the requirements of section 321 are received by the Director that have not been dismissed as provided in this subsection (a), an opposition proceeding shall be promptly instituted, but not prior to nine months after the date of grant of the patent. The Director may dismiss an opposition request that the Director determines lacks substantial merit. The determination by the Director to dismiss shall not be appealable. The dismissal of an opposition request shall not be admissible in any civil action related to the patent against which a dismissed request was filed. If the opposition is instituted based upon more than one opposition request, the opposition shall proceed as a single consolidated proceeding, unless later divided as provided in subsection (b).

(b) The parties to the opposition proceeding shall be the patent owner and each opposer whose request meets the requirements of section 321 and has not been dismissed under subsection (a). The Director shall assign the opposition proceeding to a panel of three administrative patent judges, hereinafter in this chapter referred to as the "panel." The panel shall decide the questions of patentability raised in each opposition request for which an opposition has been instituted. The decision shall be based upon the prosecution record that was the basis for the grant of the patent and the additional submissions by the parties to the opposition proceeding authorized under this chapter. The panel may, in appropriate cases, divide the opposition into separate proceedings if the opposition involves multiple opposition requests by different parties.

§ 326. Patent owner response

After the Director has instituted an opposition, the patent owner shall have the right to file a response to each opposition request within the time period set by the panel. The patent owner, in responding to an opposition request, shall file with the response any additional factual evidence and expert opinions on which the patent owner relies in support of the response through affidavits or declarations.

§ 327. Amendment of claims

The patent owner is entitled to request amendment of any claims that are the subject of the opposition, including by the addition of new claims. Any such request for amendment shall be filed with the patent owner's response to an opposition request. The panel may permit further requests for amendment of the claims only upon good cause shown by the patent owner. No amendment enlarging the scope of the claims of the patent shall be permitted in the opposition.

§ 328. Discovery and sanctions

(a) After institution of an opposition, the patent owner shall have the right to depose each person submitting an affidavit or declaration on behalf of any opposer, and each opposer shall have the right to depose each person submitting an affidavit or declaration on behalf of the patent owner. Such depositions shall be limited to cross-examination on matters relevant to the affidavit or declaration. The panel shall set the times for taking the deposition of any affiant or declarant. No other discovery shall be permitted unless the panel determines that additional discovery is required in the interest of justice.

(b) In the event that any party to an opposition fails to properly respond to any discovery under this section, the panel may draw appropriate adverse inferences and take other action permitted by statute, rule, or regulation.

§ 329. Supplemental submissions

The panel may permit one or more supplemental submissions to be made by any party to the opposition, subject to the rights and limitations on discovery described in section 328.

§ 330. Hearing and briefs

Any party to an opposition may request an oral hearing within the time set by the panel. If a hearing is requested or the panel determines *sua sponte* that a hearing is needed, the panel shall set a time for the hearing. The panel may permit the filing of briefs by the parties, and shall permit cross-examination of all affiants and declarants, either before the panel or by deposition taken under section 328.

§ 331. Written decision

The panel shall issue a written decision on each issue of patentability with respect to each claim that is the subject of the opposition. The written decision shall consist of findings of fact and conclusions of law. The written decision shall become a final determination of the Office on the issues raised in the opposition unless a party to the opposition files a request for reconsideration and modification of the written decision within a time set by the panel, which period shall not be less than two weeks from the date of the written decision.

§ 332. Burden of proof and evidence

(a) The opposer shall have the burden to prove invalidity of a claim by a preponderance of the evidence. The determination of invalidity shall be based upon the broadest reasonable construction of the claim.

(b) The Federal Rules of Evidence shall apply to the opposition proceeding, except to the extent inconsistent with any provisions of this chapter.

§ 333. Reconsideration

If a request for reconsideration of the written decision is filed, the panel may authorize a non-requesting party to file a response to the request for reconsideration. Following any reconsideration, the panel shall either deny the request for modification of the written decision or grant the request and issue a modified written decision that shall constitute the final determination of the Office on the issues raised in the opposition.

§ 334. Appeal

A party dissatisfied with the final determination of the panel may appeal under the provisions of sections 141–144. Any party to the opposition shall have the right to be a party to the appeal.

§ 335. Certificate

When the time for appeal has expired or any appeal proceeding has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and shall incorporate into the patent any new or amended claims determined to be patentable. The issuance of the certificate shall terminate the opposition proceeding.

§ 336. Estoppel

(a) Once the certificate has issued under section 335, the determination with respect to an issue of invalidity raised by an opposer shall be preclusive against that opposer in any subsequent proceeding involving that opposer as to any issue of fact or law actually decided and necessary to the determination of said issue, provided that, if the opposer demonstrates to a later tribunal that there is additional factual evidence that is material to an issue of fact actually decided and necessary to the final determination that could not reasonably have been discovered or presented in the opposition proceeding by that opposer, the opposer may raise that issue of fact and any determined issue of law for which the issue of fact was necessary.

(b) For purposes of this section, the term "opposer" includes the person making the request under section 321, any real party in interest, and their successors in interest.

(c) If the subsequent proceeding involves a real party-in-interest not identified to the patent owner pursuant to section 322, the real party-in-interest shall notify the Director and the patent owner of that fact and of the subsequent proceeding within 30 days after receiving notice that the subsequent proceeding has been filed.

§ 337. Duration of opposition

The final determination described in section 333 shall issue not later than one year after institution of the opposition as described in section 325. Upon good cause shown, the Director may extend the one-year period by not more than six months.

§ 338. Settlement

(a) The opposition proceeding shall be terminated as to any opposer upon the joint request of the opposer and the patent owner, unless the panel has issued a written

decision under section 331 before the request for termination is filed. If the opposition is terminated as to an opposer under this section, no estoppel under section 336 shall apply as to the terminated opposer. The written decision under section 331 shall thereafter be issued only with respect to issues of invalidity raised by opposers that remain in the opposition.

(b) Any agreement or understanding between the patent owner and an opposer, including any collateral agreements referred to therein, made in connection with or in contemplation of the termination of the opposition, shall be in writing. The opposition as between the parties to the agreement or understanding shall not be terminated until a true copy of the agreement or understanding, including any such collateral agreements, has been filed in the Office. If any party filing an agreement or understanding requests, the agreement or understanding shall be kept separate from the file of the opposition, and made available only to Government agencies on written request, or to any person on a showing of good cause.

(c) Any discretionary action of the Director under subsection (b) shall be reviewable under section 10 of the Administrative Procedure Act.

§ 339. Intervening rights

Any proposed amended or new claim determined to be patentable and incorporated into a patent following an opposition proceeding shall have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, prior to issuance of a certificate under the provisions of section 335.

§ 340. Relationship with reexamination proceedings

A patent for which an opposition proceeding has been instituted may not thereafter be made the subject of a request under section 311 for inter partes reexamination by the same opposer or on behalf of the same real party in interest. An ex parte reexamination request made by a person other than the patent owner during the nine-month period specified in section 323, or an inter partes reexamination request made during the nine-month period specified in section 323, shall be treated as a request under section 321, and no ex parte reexamination or inter partes reexamination may be ordered based on such request. A request for ex parte reexamination or inter partes reexamination made after the nine month period specified in section 323, and a request for ex parte reexamination made by the patent owner at any time, shall be stayed during the pendency of any opposition.

Mr. SMITH. Thank you, Mr. Kirk.

Mr. Sun?

TESTIMONY OF KARL SUN, SENIOR PATENT COUNSEL, GOOGLE, INC.

Mr. SUN. Mr. Chairman, Ranking Member Boucher and Members of the Subcommittee, thank you for the opportunity to testify at today's hearing.

Google takes pride in its ability to provide innovative products and services to help organize the world's information and to make it usable and accessible to all. We therefore believe that a properly-functioning patent system rewards inventors by providing a limited right to exclude. At the same time, we also strongly believe that the current patent system needs reform to ensure that competition and innovation are not stifled by the issuance of invalid patents.

We believe that reforms need to recognize and address the practical realities of the patent system, including the accelerating rate of patent filings, an overworked and understaffed PTO examining corps, and fundamentally, the ex parte process by which patents are granted.

Google supports reforms that create proper incentives for applicants and the Patent Office during the examination process provide for increased third-party involvement in a post-grant administrative review process and that allow subsequent judicial review, each

of which steps are tailored to the particular challenges of the patent process.

We believe that a post-grant opposition procedure would enhance the quality of patents granted under an otherwise ex parte examination system. We believe that a successful post-grant opposition procedure would have a number of important components. First, a post-grant opposition procedure should offer third parties a meaningful opportunity to challenge the validity of issued patents. As a point of comparison, parties right now do employ the current inter partes reexam procedure because of several concerns, including, as mentioned here, the limited right to participate in the process and also the broad estoppel that results.

Accordingly, we believe that the new opposition procedure would give opposers a real opportunity to participate by providing for limited discovery, expert testimony, oral argument and cross-examination and that this would occur before patent administrative law judges who are trained in the law and who are independent of the examining corps.

Additionally, we believe that an opposition process should allow challenges based on any patentability grounds, not merely the lack of novelty and obviousness as is the case with the current inter partes reexam. Second, estoppel arising from patent opposition should be limited to the grounds that are raised and addressed in the opposition. Again, as a point of comparison, the broad preclusive effect currently given in inter partes reexamination is a significant disincentive for its use. At the same time, failure to oppose a patent should not have any bearing in potential later litigation, because parties should not be given artificial incentives to oppose patents.

Third, to prevent harassment of patentees, opposition should be initiated within certain limited time periods. For example, as one possibility, allow opposition by any party during an initial 1-year period following the issuance of patent claims. However, because many third parties generally do not become aware of patents until they are notified by a patentee, consider giving these third parties an additional window of time within which to initiate opposition after they have received notice or threat of litigation.

With such a system, after the initial period, patentees will have certainty that their patent cannot be opposed, except by third parties whom they themselves notify and threaten with infringement.

Fourth, we believe that a presumption of validity should only be given to patents that have undergone the opposition process. There is general agreement that patent examiners need more time to examine applications. Current estimates for the total time that an examiner spends on average per patent application from start to finish range from between 8 to 25 hours. Moreover, patent examination is conducted as an ex parte process between an examiner and the applicant with no third party involvement currently.

Finally, examiners are rated according to a system that creates incentives for granting patents. Patents which are issued by an overburdened PTO without inter partes safeguards as to quality should not be accorded a presumption of validity courts.

In addition to these observations on the mechanics of post-grant opposition, we would also like to suggest just a couple of additional

points for future consideration by the Subcommittee. First, consider requiring patent applicants to disclose the relevance of prior arts submitted to the PTO. This would simultaneously relieve examiners from the burden of attempting to decipher the relevance of prior art that the applicant submits and would also discourage applicants from dumping art of questionable relevance on the PTO.

Second, consider providing prior use rights or similar protection from claims that are opportunistically broadened in continuation practice. Third, increase funding for the PTO so that examiners' work loads may be reduced. And finally, consider modifying the PTO rating count system to remove artificial incentives to grant patents. Instead, a system that provides neutral incentives can be implemented.

Once again, thank you for the opportunity to testify today on this important topic.

[The prepared statement of Mr. Sun follows:]

PREPARED STATEMENT OF KARL SUN

Chairman Smith, Ranking Member Berman, and Members of the Subcommittee, thank you for the opportunity to testify at today's hearing on the role of post-grant opposition in improving patent quality. My name is Karl Sun and I am Patent Counsel at Google.

BACKGROUND

Google takes pride in its ability to provide innovative products and services to help organize the world's information, and to make it accessible and useful for people everywhere. We believe that a properly functioning patent system rewards inventors by providing a limited right to exclude, and thereby promotes innovation. At the same time, Google also strongly believes that the current patent system needs reform to ensure that competition and innovation are not stifled by the issuance of invalid patents.

Reforms need to recognize and address the practical realities of the patent system, including the burgeoning rate of patent filings, an overworked and understaffed examining corps, and the *ex parte* process by which patents are granted. Google supports reforms that create proper incentives for applicants and the patent office during pre-grant examination, that provide increased third party involvement in post-grant administrative review, and that allow subsequent judicial review tailored to the unique challenges of the patent process.

RECOMMENDATIONS

Google believes that a post-grant opposition procedure would enhance the quality of patents granted under an otherwise *ex parte* examination system. A successful post-grant opposition procedure would have a number of important components.

- First, we are in favor of a post-grant opposition process and/or a substantially revised *inter partes* reexamination process that offers third parties a meaningful opportunity to challenge the validity of issued patents. Parties do not employ the current *inter partes* reexamination procedure because of several concerns, including their limited right to participate in the process and the broad estoppel that results.
- Accordingly, the new opposition procedure should give opposers a real opportunity to participate by providing for limited discovery, expert testimony, oral argument, and cross-examination before patent administrative law judges who are independent of the examining corps. Additionally, an opposition process should allow challenges based on any patentability grounds, not merely lack of novelty and obviousness as is the case with the current *inter partes* reexamination procedure.
- Second, estoppel arising from patent opposition should be limited to grounds that are raised and addressed in the opposition. In addition, failure to oppose a patent should not have any bearing in later litigation. The broad preclusive effect currently accorded to *inter partes* reexamination is a disincentive for its

use and should be reconsidered; at the same time, parties should not be given artificial incentives to oppose patents.

- Third, to prevent harassment of patentees, opposition should be initiated within prescribed time periods. As one possibility, allow opposition by any party during an initial one year "quality control" period following the issuance of patent claims. After the initial period, patentees may be entitled to some certainty that their patent cannot be opposed, except by third parties whom they themselves notify and threaten with infringement. Because third parties generally do not become aware of patents until notified by a patentee, these third parties may be given an additional window within which to initiate opposition.
- Fourth, a presumption of validity should be given only to patents that have undergone the opposition process. There is general agreement that patent examiners need more time to examine applications. Current estimates for the *total* time an examiner spends per patent application from start to finish range from 8 to 25 hours on average.[1] Moreover, patent examination is conducted as an *ex parte* process between an examiner and an applicant, with no third party involvement. Finally, examiners are rated according to a "count" system that creates incentives for granting patents. Patents which are issued by an overburdened PTO without *inter partes* safeguards as to quality should not be accorded a presumption of validity by the courts.

In addition to the above observations on the mechanics of a post-grant opposition process, Google would also like to suggest the following additional patent reforms for future consideration by the subcommittee:

- First, we should require patent applicants to disclose the relevance of prior art submitted to the PTO. This simultaneously relieves examiners of the burden of attempting to decipher the relevance of prior art submitted by the applicant, and discourages applicants from "dumping" art of questionable relevance on the examiner.
- Second, provide prior use rights or similar protection from allegations of infringement based on claims that are opportunistically broadened in continuation practice.[2]
- Third, increase funding for the PTO so that examiners' workloads may be reduced to allow an adequate amount of time for considering patent filings.
- Finally, modify the PTO count system to remove artificial incentives to grant patents. Patent examiners are rated according to a point or "count" system that encourages patent issuance.[3] A system that provides neutral incentives with respect to allowance versus rejection should be implemented.

CONCLUSION

Thank you again for the opportunity to testify today and to share Google's perspective on this important topic.

Mr. SMITH. Thank you, Mr. Sun.

Mr. Toupin, let me address my first question to you, and that is, well, first of all, let me observe that it is amazing to me that there is general agreement on the need for post-grant opposition, and there is general agreement at least—yes, general agreement on a lot of suggestions as well, which makes this panel one of the most agreed and agreeable that we've had, I think.

But, Mr. Toupin, my question for you is that it seems to me that we might really supplement rather than replace the current reexamination system that we have right now. We are talking more about post-grant today, but don't you think we ought to take the best of the present and combine it with a lot of your suggestions for the post-grant opposition?

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[1] *See* Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (October 2003) (hereinafter *FTC Report*), ch. 5 at 4–5.

[2] *See, e.g., FTC Report* ch. 4(II)(C)(1) at 26–31.

[3] *See, e.g.,* Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform,* 14 Berkeley Tech. L.J. 577, 609 (1999).

Mr. TOUPIN. The 21st Century Strategic Plan suggests that inter partes reexam be abandoned; that it is not going to be effective for the reasons that have been indicated.

Mr. SMITH. So you would for replacement, not supplement.

Mr. TOUPIN. Replacement in that respect. With respect to third party initiated ex parte reexamination, I believe that we suggest some form of discretion with respect to third-party initiated reexams might be appropriate if you also have a post-grant review but maintaining that system.

Mr. SMITH. Okay; fair enough, thank you.

Mr. Kushan, you may have been the only witness to have mentioned privatization, although you didn't use that word. You suggested that we, let's see, in the case of arbitration of specified issues that we perhaps private parties as a cost-saving measure. Would that unnecessarily complicate matters, or would that streamline matters?

Mr. KUSHAN. One of the things that motivated that recommendation was the recognition of uncertainty in the funding of the office uncertainty and complexity of these proceedings, and we draw on our experience in litigation where we are able to offload some issues for resolution.

There's also some experience in the PTO in interference proceedings where there is some capacity to do a bit of an offloading exercise. To some extent, if there is a way of delegating to an entity or allowing the parties resolve certain factual issues as part of this proceeding, we believe that this would facilitate and essentially control the volume of work that's associated with any one proceeding, and it is typically encountered in litigation where you sort things out.

But we were trying to find ways of putting some type of safeguards into the system, because we know that there are going to be proceedings which are going to be extremely complex, and we see a risk of having these proceedings start and essentially paralyzing the patent for an indefinite period.

Mr. SMITH. Thank you, Mr. Kushan.

Mr. Kirk, it is clear to me that certainly, large corporations are going to benefit from post-grant opposition, but would smaller businesses and independent inventors benefit as much as the larger corporations?

Mr. KIRK. Mr. Chairman, I think that the fact that we can provide an attractive procedure that would determine the validity of claims of issued patents more efficiently, more effectively, quicker, than District Court litigation, which, as I noted, runs into the millions of dollars, is going to help large and small companies but especially the small company and the independent inventor.

Mr. SMITH. Thank you, Mr. Kirk.

And Mr. Sun, you suggested in your written testimony that only patents that have been challenged in an opposition proceeding should be entitled to a presumption of validity. Isn't that a pretty tough standard? And why would that be justified to, in effect, make that requirement?

Mr. SUN. Well, Mr. Chairman, I think we believe that with the way the current system is set up, with the ex parte process, what the PTO is doing and what we probably wanted to do was to do

the initial pass of making sure that there is nothing clear out there that would preclude the issuance of a patent. But I think what we are talking about here including with the post-grant opposition process is that right now, there is something fundamentally wrong with the system, which is that patents are making their way through which should not have been granted in the first place.

And given that that is the reality, we think that it is not justified that patents all receive a presumption of validity in the situation where we all acknowledge that there are many patents being questioned.

Mr. SMITH. Thank you, Mr. Sun.

That completes my questioning, and the gentleman from Virginia, Mr. Boucher is recognized for his.

Mr. BOUCHER. Well, thank you very much, Mr. Chairman. I want to say at the outset that I share Chairman Smith's pleasure through the fact that we have parties appearing today who, shall we say, are not always in agreement when it comes to matters of patent policy, and today, I am pleased to note a broad area of agreement on a number of matters.

I actually took the opportunity to synthesize and place in chart form various aspects of each of your testimony, and this chart reveals a very interesting fact, and that is on three broad areas, there is basic agreement. Now, I think there may be some shading differences with regard to how you would do each of these three things, but I detect basic agreement on these matters.

First of all, you are all in favor of post-grant opposition and having a legislated process for putting that into place. Secondly, I note that each of you favors the general requirement that all patent applications be published after 18 months. Now, I've always thought that was good, particularly if you had some kind of window inside the patent review process itself for the opportunity for third parties to submit evidence of prior art.

Obviously, if they don't know a patent application is pending, they wouldn't have any reason to submit the prior art, and the publication serves the very valid function of providing that notice. As I indicated in my opening statement, we have some substantial problems in getting that adopted in the House. That actually was tried once before, and we were not successful for reasons I will not dwell on today. Why give your opponents publicity?

But it is difficult, and it may be as difficult now as it was four or 5 years ago, the first time we undertook that exercise. Nevertheless, I think it is beneficial. But, you know, you need it less if you know you have got a really good post-grant opposition process, because by the time the patent is awarded, notice is automatically provided. Anybody who has got prior art and is paying attention would then be in a position through the post-grant opposition process to have that evidence of prior art or other matters that might affect the validity of the patent be submitted.

Nevertheless, I still think publishing after 18 months is in theory a good idea. I notice all of you were in agreement.

The third area in which I notice agreement among each of you is with respect to making modifications in the current process for inter partes reexamination. I guess I just have a basic question, and that is this: if we put into place a really good post-grant oppo-

sition proceeding, and it meets the standard of providing a fair opportunity for anyone who has got a legitimate basis for challenging a patent to come in and make his case and have administrative law judges perhaps within the Patent Office make a determination, why should we also retain the inter partes reexamination process?

Why have two avenues through which these matters can be raised? Is there any value in keeping that second door open? Is there a category, perhaps, of individuals who might find the post-grant process to be unduly burdensome or perhaps unaffordable who might want to take advantage of a more simplified and less formal inter partes reexamination?

I don't know, and so, I will ask you that question. I note that each of you is basically recommending keeping it, possibly as modified by what Mr. Toupin said during his response to the Chairman's question, but I would be interested in hearing your views on why we need to keep both of these avenues open.

Mr. Kirk?

Mr. KIRK. Let me step in first if I might, Mr. Boucher. From our perspective, we have discussed this, and our viewpoint was first, we would like to see an effective post-grant opposition system in place and operating, to see it implemented and working properly. Once that is in place, and we are comfortable that it can be implemented properly and is working the way we had intended, then, I think we would certainly want to turn our attention to the post-grant—to the inter partes reexamination system to see how that might be changed in the future, keeping in mind that most of the proposals for post-grant discuss having a limited period, 9 months in our case, 1 year in others.

There needs to be some mechanism after that period for effectively challenging the patents, and given an opposition system that works properly, I think that could be worked out, and then, perhaps, inter partes reexamination would just disappear. But we sort of take the approach of "let us see if it works first" before we start throwing things out.

Mr. BOUCHER. So you were saying if you time-limit the post-grant opposition proceeding, you would need some other avenue to remain open, perhaps indefinitely, for individuals who may not have been in a position to challenge within the window of the post-grant proceeding.

Mr. KIRK. That is true, but that can also be accomplished by, for example, as the PTO suggested, having an open window following, for example, a threat sufficient to establish declaratory judgment standing so that they then could bring a proceeding within a period of time.

Mr. BOUCHER. But it would be triggered on some event such as that; is that correct?

Mr. KIRK. Well, that is one way of doing it. I would not want to say that this should be the only way of doing it. I think again, we have to wait and see. How well does it work? How expensive is it? How fast is it? Once we understand that and see that, I think many changes could be made.

Mr. SMITH. Without objection, the gentleman is recognized for an additional 2 minutes so the other witnesses can respond to the question.

Mr. BOUCHER. Thank you, Mr. Chairman.

Mr. Kushan?

Mr. KUSHAN. I think one way to look at the two regimes is kind of a bare bones and a deluxe proceeding, with the difference in the concept of opposition being that you get additional evidentiary procedures put at your disposal so you would be able to depose or cross-examine witnesses that are being advanced to throw their views into the mix. You can get a hearing, things of that nature.

One benefit at least conceptually not in the system as implemented but conceptually of the inter partes regime is that it is a simpler proceeding, and it may be suitable for settings where you have really clear-cut issues of patent validity. Maybe the best perspective is to absorb the simplified process into a structure which is basically the opposition proceeding and then allow the judge that is going to be conducting the proceeding to decide exactly how much discovery is needed.

I think one concern we have had, and it is in our written testimony, there are some types of discovery which we think should definitely be avoided in an opposition proceeding, which if you allow them to go into that proceeding would essentially eliminate the difference between that and litigation.

And so, perhaps one perspective to take to this is to envision a simplified pathway within the authority to conduct the more rigorous proceeding which allows the additional evidentiary tools.

Mr. BOUCHER. Okay; Mr. Sun, would you care to comment?

Mr. SUN. Sure. Congressman, I think I would echo what Mr. Kirk said, which is I think our position is that the first point to be made is that the post-grant opposition is one that is a more robust procedure and is one that we would like to see put in place.

After that is in place, it may well be the case that an inter partes reexam is a good complement to the opposition procedure. And it is possible that many times, it will be the case that it will not be necessary. But I can envision a system where the inter partes reexam continues to be a documentary-based procedure where it is conducted before an examiner as opposed to a patent judge, so it would, in many senses, be simpler for someone who wants to challenge that process, and it may well be the case, as you mentioned, that that is an avenue that some people would still want to take advantage of. But I think it remains to be seen.

Mr. BOUCHER. Well, thank you each for those answers.

I just have one other brief question. This can be a yes or no. In fact, I hope it is, because my time is up. Would you each agree that as we set about this task, we should be guided by the principle that in repairing the inter partes reexam, we should eliminate the estoppel concept? That is part of the question. The other part is in the post-grant opposition proceeding, should the standard of proof simply be preponderance of the evidence?

Can I get a yes from each of you with regard to those questions?

Mr. Kirk?

Mr. KIRK. Yes.

Mr. BOUCHER. Excellent.

Mr. Kushan?

Mr. KUSHAN. Yes, on the first one, and the second one is maybe a little bit more complicated, but generally, it should be once you get the proceeding started, yes.

Mr. BOUCHER. Okay; all right.

Mr. Toupin?

Mr. TOUPIN. As to the first, we have a different solution to inter partes reexam, so I can't answer yes or no on that one. With respect to the second one, yes, we contemplate once a proceeding was underway, it would be preponderance.

Mr. BOUCHER. Okay.

And Mr. Sun?

Mr. SUN. Yes.

Mr. BOUCHER. Thank you very much.

Thank you, Mr. Chairman.

Mr. SMITH. Good question, Mr. Boucher. Thank you.

And the gentlewoman from California, Ms. Lofgren, is recognized for her questions.

Ms. LOFGREN. Thank you, Mr. Chairman and thanks to the witnesses for their excellent testimony. And as the Chairman and Ranking Member, or today's Ranking Member, have mentioned, there is actually remarkable agreement on the basic outlines of what we should do. As many of you know, in 2001, I had a patent reexamination bill that would have expanded the existing procedure by enlarging the scope of challenges and also setting a 12-month deadline and changing the estoppel issue by allowing third parties to later introduce evidence which was not known at the time of the proceeding.

And in talking to people, I reached the conclusion that it would not necessarily be useful to reintroduce that bill because of this process that is moving forward, although I think there are some elements that are certainly similar and some things that go beyond that concept of a few years ago.

One of the benefits of being last in the questioning is that all of your questions have already been asked, and so the remaining question that I have that has not already been asked by Mr. Smith and Mr. Boucher really has to do with the evidentiary load.

I mean, it is a fine line between providing sufficient opportunity to really flush out the information without destroying the ability to have a streamlined procedure by having too much process. And I am just sort of wondering, what should we make available to the parties? I mean, shouldn't we allow for depositions? Shouldn't we allow for interrogatories? How would we limit that? How do we get the information out without destroying this whole new innovation? Do you have thoughts on that for us to ponder or at least benchmarks on how we would approach that question?

Any of you? Maybe I'll go to—Mr. Kushan wants to answer first; and I'd like to hear from all of you on that point.

Mr. KUSHAN. This is definitely an important variable in the design of the system, because if you let things run amok, it scares people, particularly patent owners, from either supporting this type of regime or not. I think if you look at the environment of a post-grant proceeding, you have the benefit of someone who can evaluate issues at a technical level in a very good, in an accurate way,

so you have the benefit of an expert listening to the technical arguments.

I think it is a fairness issue to be able to cross-examine or depose someone who has been put up by the other party into the proceeding. We don't want to see the proceeding give an authority to call out witnesses and to make it a litigation-like process, where you are essentially trying to pull all the stuff into the proceeding. That would, I think, cross the line.

There may be some value for interrogatories and requests for admissions. I think that would be something that should be left in the hands of the APJ to assess whether that is necessary in the proceeding. Again, this is an objective question that they are answering a validity, and they have, at the Patent Office, an ability to answer that on their own.

So you can use that inherent advantage that they have.

Ms. LOFGREN. Do you agree with that, Mr. Kirk?

Mr. KIRK. I think we are generally in the same area on this. I think there are two issues that are related. One is the breadth of the issues that you can allow to be considered in the post-grant opposition, the extent to which you are going to allow evidence to come in, and what type of evidence. We certainly think it would be proper to have affidavits, depositions, to be able to cross-examine by affidavits and depositions the witnesses of the other party, and to have that come forward.

You get into certain issues, for example, best mode, which is very subjective, and it is in the inventor's mind. This kind of an issue, which is raised frequently in court, requires a great deal of discovery. Usually, it doesn't result in any invalidity finding, but nevertheless it occupies a lot of time in court and a lot of expensive discovery. That we believe should be kept out, the issue and with it the discovery that one might need to really fairly evaluate that.

So you are compromising on the one hand enough evidentiary flexibility to encourage people to use the system; on the other hand, not so much that you would harass that——

Ms. LOFGREN. That is an interesting approach. I hadn't really thought of that.

Mr. Toupin and Mr. Sun, do you have further comments? I realize I'm almost out of time.

Mr. TOUPIN. Thank you. We think that there are three elements that work in this. First, there has to be a substantial initial showing generally in the line of a prima facie case. That would allow an APJ to closely define what issues would be subject to discovery. We don't recommend that either the tools of discovery or the substance that would be available for inquiry be limited.

We currently have experience with the full range of patentability issues being able to be raised in interference proceedings. These APJs know how to do it and know how to do it expeditiously.

Ms. LOFGREN. You are cleanup, Mr. Sun.

Mr. SUN. I was just going to add what was just said, which is in the interference proceeding, I think there already is some mechanism there. I think we would also be in agreement that the amount of process is in some sense dependent on the scope of what can be covered, and we would be in favor of a lot of the 112 issues being in play, and so, there would be a need for a similar process,

but we think the combination of the APJs being able to have power to handle discovery as well as the expertise that already exists; things should be manageable in that fashion.

Ms. LOFGREN. Thank you very much, and thank you, Mr. Chairman.

Mr. SMITH. Thank you, Ms. Lofgren.

Let me thank all the witnesses. This has been particularly informative for us and a particularly helpful panel. And as I mentioned in my opening statement, we will use your testimony to draft legislation which we expect to take up if not immediately then sometime within the next several months, I would hope. And so, it is not often we have hearings that lead directly to legislation, and it's not often that we have so many panelists that agree generally on the direction we should take, so it's much appreciated, and we thank you all for being here, and with that, we stand adjourned.

[Whereupon, at 5:18 p.m., the Subcommittee adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

PREPARED STATEMENT OF THE HONORABLE JOHN CONYERS, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN, AND RANKING MEMBER, COMMITTEE ON THE JUDICIARY

There has been a long debate in the patent community on whether the United States should implement a new system for challenging patents after they have been issued, otherwise known as post-grant opposition. This system would be broader than the reexamination process that exists now. While there are strong arguments in favor of an opposition system, there are policy questions that should not be ignored.

It cannot be denied that the patent laws are a major incentive for investment and research into new technologies, whether the field is life-saving drugs, computers, or a new method of transportation. Because patents may discourage competition, we rely on the Patent and Trademark Office to make sure that the patents it issues are narrow and clear. Because developments in technology has exploded in recent years, information is widespread, and applications are up, it is difficult to properly review every application in a timely manner. If investors and researchers cannot rely on the validity of patents, either someone else's or their own, then the flow of ideas and capital will be severely restricted.

That is why it is vitally important for the PTO to be able to correct patents even after they have been issued. While we do have such a system in place, known as reexamination, the process is unwieldy and limited. That is why there has been broad support for the new opposition proceeding. We must allow for third parties to be more involved than they are in reexaminations, for appropriate evidence to be introduced, and for broader patent eligibility questions to be asked.

As I stated earlier, though, I do have concerns. The only reason we are thinking of making it easier to challenge patents is because there is a problem of bad patents being issued. If we are going to address this problem, though, we must not only make it easier to challenge them but also prevent them from being issued in the first place. In other words, I hope that a movement toward post-grant opposition will not deter our efforts from making sure the PTO has what it needs to review patent applications thoroughly the first time.

Second, if we do establish an entirely new type of proceeding, it is important to consider what resources will be required at the PTO. The PTO has made a push for outsourcing many of its functions on the grounds that it does not have enough trained personnel to concentrate on its core function of evaluating applications. If it does not have the resources now, I wonder what strains an opposition system would create.

LETTER TO REP. LAMAR SMITH AND REP. HOWARD L. BERMAN FROM STEPHAN H. LAWTON, VICE PRESIDENT AND GENERAL COUNSEL, BIOTECHNOLOGY INDUSTRY ORGANIZATION

July 8, 2004

The Honorable Lamar Smith
Chairman
Subcommittee on Courts, the Internet and Intellectual Property
Committee on the Judiciary
B351A Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

The Honorable Howard Berman
Ranking Minority Member
Subcommittee on Courts, the Internet and Intellectual Property
Committee on the Judiciary
B336 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman and Mr. Berman:

The purpose of this letter is to express the views of the Biotechnology Industry Organization ("BIO") for the written record of the Subcommittee's recent oversight hearing held on June 24, 2004, on "Patent Quality Improvement: Post-Grant Opposition." BIO is a trade association of more than 1,000 companies, universities, research institutions and affiliated organizations engaged in biotechnology research on medicines, diagnostics, agricultural products, pollution controls and industrial applications.

Our members are important stakeholders in patent system reform because the biotechnology industry was built on the ability to protect truly breakthrough inventions. To understand the importance of the patent system to BIO's constituents, it is important to understand the biotechnology industry.

About the Biotechnology Industry

The biotechnology industry is very research intensive. The U.S. biotechnology industry spent more than $20.5 billion on R&D in 2002, with the top five companies spending an average of $101,200 per employee on R&D. The biotechnology industry is also a dynamic one. There are over 1,400 biotechnology companies in the U.S. employing over

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190,000 people. This nascent industry has produced more than 370 biotech drug products and vaccines currently in late stage clinical trials that target more than 200 diseases. Some biotechnology products such as EPO, Herceptin® and Xigris® have revolutionized the way our society deals with cancer and other chronic diseases. Biotechnology is responsible for hundreds of medical diagnostic tests, which encompass everything from keeping the blood supply safe from AIDS to home pregnancy tests. Industrial biotechnology applications have led to cleaner processes that produce less waste and use less energy and water. Consumers are already enjoying biotechnology foods. However, those in the biotechnology community know that this is just the beginning. The biotechnology industry is one of the most innovative industries in the U.S. economy. The biotech sector filed over 40,000 new biotechnology patent applications with the United States Patent and Trademark Office (PTO) in fiscal year 2003 and this trend is expected to continue. BIO members have developed and will continue to develop products that have great impact on patients and consumers.

The Role of Patents in the Biotechnology Industry

Biotech companies operate in an ecosystem of federal funding of basic and applied research, intellectual property law (particularly patent law), technology transfer, collaborative activities and private investments for financing. Patents serve as a stimulus for inventiveness and creativity. Investors recognize patents as important benchmarks of progress in developing product lines and revenues. Investment provides the life-blood of a very research-intensive industry, and intellectual property protection serves as the enticement for private financing. The promise of a return on investment, rooted in patents on biotechnology inventions, helps to attract capital in these high-risk biotechnology products.

Indeed, many start-up biotechnology companies have been created based solely on the promise of their patent estates. The vast majority of biotechnology companies do not have products on the market; rather they have only patents on what may eventually become a commercially viable product or technology. This intellectual property protects the assets that entice investment for further development of a promising technology or product. The capital generated as a result of this intellectual property supports companies as they invest the hundreds of millions of dollars and the decades necessary to develop a commercial biotechnology product.

Strong domestic and international intellectual property protections have been, in large measure, responsible for the growth and development of today's biotechnology industry. Confidence in the patent system by the innovation sector, the investment community and the consuming public is especially important. Accordingly, BIO is not only attuned to the merits of the patent system but recognizes the importance of patent quality improvements as well. BIO believes that an effective patent system stimulates innovative biotechnology discoveries and inventive activities that benefit the American public, be it healthcare patients, farmers, consumers of food products or industrial workers, among others.

On behalf of BIO, I commend you and your subcommittee for its stalwart leadership on patent law issues and for already shepherding through the House of Representatives during the 108th Congress two patent reform measures supported by BIO: the Patent Fee Modernization Act and the Cooperative Research and Technology Enhancement (CREATE) Act. Both will contribute, if enacted, to a higher quality patent system.

Your oversight inquiry into a post-grant review process must inevitably consider whether the process will promote quality improvements without unduly eroding patent owner rights and thereby chilling innovation. The Subcommittee no doubt will consider proposals to establish an open-review procedure, enabling third parties to challenge the validity of issued patents on any grounds in an administrative proceeding within the PTO for a limited period. *See, e.g.,* H.R. 1333 (The Patent Improvement Act of 2001), 107th Cong., 1st Sess. (2001) (introduced by Mr. Berman); Report of the National Academy of Sciences on "A Patent System for the 21st Century" (2004) at 78; Report of the Federal Trade Commission on "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" (October 2004) at Executive Summary, p. 7, and Chapter 5, pp 17-18; "The 21st Century Strategic Plan," "Post-Grant Review of Patent Claims" (PTO, April 2, 2003) at 1. PTO at 14: and Recommendations of the American Intellectual Property Law Association (Oversight Hearing on "Patents: Improving Quality and Curing Defects" Before the Subcomm. on Courts, the Internet and Intellectual Property of the House Comm. on the Judiciary, 107th Cong., 1st Sess. 31-42 (2001) (statement of Michael K. Kirk, Executive Director).

As the Subcommittee is aware, both the Federal Trade Commission and the National Academy of Sciences (NAS) recently released reports that raise concerns with respect to the quality of certain patents and recommend areas where legislation may lead to improved patent quality. BIO strongly supports efforts to make the U.S. patent system more predictable and patent rights more certain and dependable through quality improvements. The more certain the law concerning the validity and enforceability of patent rights, the more likely it is that our member companies will be able to attract capital and assure investors that they will deliver a sufficient return on investments. We believe a variety of legislative reforms are necessary to accomplish this goal, and strongly encourage the Congress to actively pursue these reforms.

However, as with any effort at reform, we have some concerns about approaching major changes to the U.S. patent laws in a piecemeal manner. This is especially important given that the NAS' four-year study of the U.S. patent system suggests a collection of reforms to U.S. patent laws that are fundamental and systematic. We therefore remain optimistic that the recent hearing is only the first in a series of efforts to best understand how a coordinated and comprehensive look at changes to U.S. patent laws might be achieved in a synergistic and balanced manner to realize the goal of a more predictable, affordable, certain and prompt-acting patent system. While a post-grant review procedure is an important piece of the puzzle of patent reform, it is not the only important piece. Indeed, its enactment would make other changes to the U.S. patent laws more important and more urgent.

BIO's Position on Post-grant Review
Before addressing the specific features that are needed to make any post-grant review system viable and balanced, BIO wishes to emphasize two important predicates.

Significant Funding

First, BIO believes the Congress must address the longstanding issue of PTO financing. The PTO must have available to it – on a consistent, year-in, year-out basis –the assured financial resources needed to conduct within the Office *thousands* of contested proceedings. No proposed post-grant review can discharge its policy objectives unless it is administered in a fair, balanced and prompt manner within the PTO.

To date, the appropriations process has not succeeded in ensuring predictable and adequate funding for the PTO for its existing programs. A post-grant review procedure will entrust within the PTO new responsibilities that will force the Office to secure the services of hundreds of highly skilled administrative patent judges. We therefore urge the Congress to address financing of the new post-grant review system incidental to its work in devising the appropriate elements of the system. That financing should be guaranteed. Seed money should be set aside to undertake the hiring and training of necessary personnel before the opposition law comes fully into effect.

Additional Reforms

Second, as briefly discussed above, BIO believes that in addition to enacting a post-grant review procedure, the Subcommittee should enact additional reforms to improve the patent system: to make the patent system simpler, more predictable, less expensive to use and more prompt in its resolution of issues of patentability. BIO urges the Subcommittee to consider reform recommendations 6 (significant modifications to statutes governing willful infringement) and 7 (efforts to harmonize U.S. patent laws with that of other patent systems) set out in the NAS report as a useful starting point. These recommendations are directed specifically at improving simplicity, economy, predictability and certainty.

Among other reforms, the Subcommittee should enact legislation awarding the right to a patent to the "first inventor to file." The "proofs of invention date" system in the U.S. is complex, expensive, unpredictable and time-consuming. Moreover, Congress should reduce the number of "loss of rights" conditions in U.S. law. In this regard, it is particularly important to eliminate the so-called "forfeiture" provisions in current law based on an inventor's placement of an invention "in public use or on sale" more than one year before seeking a U.S. patent. Further, the U.S. should eliminate its "subjective" "best mode" requirements and replace them with an "objective" standard. Finally, the PTO's current discretionary practice of dividing a single discovery into multiple applications must be reformed. So-called "restriction practice" is especially deleterious

for biotechnology companies, and its elimination should be an important legislative priority.

In addition, Congress should reform the law and practice of "inequitable conduct." Allegations of inequitable conduct are made in nearly every patent litigation case as an affirmative defense to alleged patent infringement. The doctrine allows the federal courts to review the *ex parte* conduct of patent applicants before the PTO. The practice has become an absolute "plague" before the courts (*see, e.g., Burlington Indus, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)) and must be reformed. Most importantly, oppositions could potentially create new opportunities for infringers to allege a patent owner's "fraud on the Patent Office," greatly increasing the burden on the patent owner in an opposition proceeding. BIO welcomes the opportunity to provide the Subcommittee with additional detail on the benefits and structure of these reforms.

BIO believes that validity issues not typically encountered by the PTO during patent examination should not be included as potential grounds for opposition in the post-grant review process, and should only be handled by the courts (e.g., best mode). It is, therefore, important to enact the comprehensive patent law reforms described above in order to complement a post-grant review process and make the post-grant review process a more viable alternative to district court litigation. By enacting BIO's proposed patent reforms, validity issues that could be determined in a post-grant review process could be made coextensive with validity issues addressed in the courts. Consequently, a favorable outcome for the patent owner in the post-grant proceeding could largely assure that a patent could be successfully defended in a later court action, thus reducing the concern that the validity of the same patents will be challenged in a post-grant proceeding and separately in district court litigation.

Minimal Requirements for New Administrative Mechanism
With these initial points in mind, BIO supports the efforts of the Subcommittee to establish a PTO-based procedure for post-grant review of the validity of patents. However, BIO's support is contingent on the system containing sufficient safeguards to ensure that it will provide a balanced, timely and accurate review of the validity of a patent, and will not become a means for third parties to harass owners of valid patents. BIO believes several elements must be present in any post-grant review procedure to ensure that it meets this general objective.

In simple terms, any post-grant review system must be timelier, less expensive and more efficient than review by the federal courts. A post-grant administrative proceeding will be valuable only if it permits a review of validity to occur without creating expenses, burdens on companies and delays comparable to those encountered in district court litigation. BIO members are concerned that an improperly structured post-grant review system may become just another place to challenge a patent and to harass patent owners. Certain procedural safeguards will be absolutely necessary to avoid this result. In this regard, the Subcommittee's expertise in the administration of justice, including alternatives to litigation, will be particularly helpful.

Because legislative proposals have not yet been introduced, BIO will identify only several minimal standards that should be incorporated in any post-grant procedure:

- Any opposition filing should be permitted only within a very limited certain period of time (e.g. 9 to 12 months from patent issuance) and the scope of post-grant review should be limited to review of validity under 35 U.S.C. § 101 (utility), §102(a), (b), (e) and (g), 103 (non-obviousness) and 112 first and second paragraphs (except for the "best mode" requirement)). Obviously, if NAS Recommendation 7 is adopted, patent oppositions could be made coextensive with patent validity issues in a court.

- Post-grant proceedings should be available for any patent within a fixed period after its grant, regardless of the actual or effective filing date of the patent.

- Opposition proceedings should only be commenced if the requestor establishes with an adequate evidentiary showing that one or more claims of the patent are *prima facie* invalid. The PTO should be required to make this initial determination before any opposition proceeding is commenced. Therefore, a frivolous request, *i.e.*, one lacking any substantial basis, should be summarily denied.

- Simplified procedures such as the existing *inter partes* and *ex parte* re-examination procedures should be preserved, either in their existing form or within the framework of a comprehensive post-grant review authority.

- Patent holders should be permitted a reasonable and limited opportunity to amend patent claims during an opposition proceeding. BIO believes that at least one amendment must be permitted as a matter of right. The PTO should manage the overall process to ensure efficiency.

- The system should require that all evidence, except patents and printed publications, be presented through affidavits and declaration testimony.

- Except if the interest of justice requires otherwise, discovery should be limited to cross examination of affiants and declarants and an oral hearing.

- Procedures should be included to prevent "ambush" tactics.

- In any post-grant proceeding, at a minimum, the real party in interest should be identified and the burden should be on the party requesting the opposition to prove invalidity.

- Any party to an opposition proceeding should be entitled to appeal a decision of the PTO to the U.S. Court of Appeals for the Federal Circuit.

- Proceedings must be completed within a statutorily specified period of time, and measures should be provided to discourage and prevent third parties from delaying or extending proceedings.

- The system should provide that a patent owner that has commenced litigation on a patent can determine the forum in which the validity of the patent will be assessed (i.e., in a district court or in a PTO post-grant review proceeding, at the decision of the patent owner);

- Measures should be included to consolidate multiple opposition requests into a single proceeding, and such measures should also preclude one entity from commencing concurrent opposition and reexamination proceedings;

- Actions of parties in a post-grant review proceeding should not be capable of creating grounds for holding a patent unenforceable. In this regard, BIO is open to proposals that would implement NAS Recommendation 6 on elimination of "inequitable conduct" as a defense to patent enforceability altogether, provided that some acceptable alternative is devised in which to define, investigate, determine, sanction and, therefore, ultimately deter misconduct before the PTO.

- No special statutory estoppel provisions should be incorporated into a post-grant review procedure, and existing statutory estoppel provisions in the *inter partes* reexamination should be removed.

BIO encourages the Subcommittee to consider the appropriateness of additional safeguards to prevent abuse of a post-grant review process.

BIO is grateful for this opportunity to submit written comments. BIO looks forward to working with you, your Subcommittee, the PTO and other interested parties in efforts to improve patent quality through carefully crafted changes to patent law.

Sincerely,

Stephan H. Lawton
Vice President and General Counsel
Biotechnology Industry Organization

LETTER TO REP. LAMAR SMITH AND REP. HOWARD L. BERMAN FROM WARNER R. BROADDUS, VICE PRESIDENT, GENERAL COUNSEL & SECRETARY, AND CHARLES S. BERKMAN, ASSOCIATE GENERAL COUNSEL AND CHIEF PATENT COUNSEL, LIGAND PHARMACEUTICALS

July 8, 2004

The Honorable Lamar Smith
Chairman
Subcommittee on Courts, the Internet, and Intellectual Property
Committee on the Judiciary
B351A Rayburn H.O.B.
United States House of Representatives
Washington, DC 20515

The Honorable Howard Berman
Ranking Minority Member
Subcommittee on Courts, the Internet, and Intellectual Property
Committee on the Judiciary
B336 Rayburn H.O.B.
Washington, DC 20515

Re: Comments of Ligand Pharmaceuticals Inc., supporting two provisions not present in BIO's comments on Oversight Hearing on "Patent Quality Improvement: Post-Grant Opposition"

Dear Mr. Chairman and Ranking Minority Member:

This letter expresses the views of Ligand Pharmaceuticals Inc. (**favoring two specific provisions to protect patent owners**) for the record of the Subcommittee's recent oversight hearing held on June 24, 2004, on "Patent Quality Improvement: Post-Grant Opposition." Ligand is an emerging high-growth bio-pharmaceutical company serving patients all over the United States, as well as the rest of the world. We discover, develop and market innovative new drugs to address critical, unmet medical needs of patients in the areas of cancer, diabetes, cardiovascular disease, and osteoporosis.

Ligand, like the Biotechnology Industry Organization (BIO), is concerned that legitimate innovators will be unjustly harassed and delayed via the post-grant opposition system if necessary procedural safeguards are not put in place. **Without such safeguards, scare capital resources of young companies will go to more and more legal fees instead of to research and development of new medical breakthroughs and other technologies.** Ligand would like to add its' general support for the comments submitted to the Subcommittee by BIO and emphasize the need for two additional and important protections for patent owners' legitimate interests, especially the interests of early stage, innovative biotechnology companies.

First, Ligand strongly believes that the patent owner must always be given the option of **removal to federal district court**. Removal would transfer a Post Grant Opposition proceeding to federal district court where normal standing and jurisdiction

requirements would apply, regardless of whether or not the patentee has already instituted suit. This is necessary in order to protect biotechnology companies, especially small ones like us, from having to defend every patent (including those covering important new drugs) in a Patent Office proceeding instituted by a party that has no legitimate interest to advance, but only seeks to harass and delay a potential competitor.

Second, Ligand strongly believes that Post Grant Opposition proceedings should only be commenced if the requestor establishes with **clear and convincing evidence** that one or more claims of the patent are invalid. Winning a patent grant from the Patent Office is an exhaustive, time-consuming and expensive process carefully designed to ensure the validity of granted patents. Overturning granted patents, therefore, should have a higher hurdle than mere preponderance of the evidence. The burden should be on the party requesting the opposition to prove invalidity under the traditional clear and convincing evidence standard applied in federal court validity challenges.

Without these two additional provisions, Ligand believes that a Post Grant Opposition system would unfairly and adversly effect small companies, to the benefit of larger companies. The Subcommittee is encouraged to consider the appropriateness of additional safeguards to prevent abuse of the opposition system. Mr. Chairman, Ligand is grateful for this opportunity to submit written comments and respectfully requests their consideration. Ligand looks forward to working with you, your Subcommittee, the PTO and other interested parties to improve patent quality.

Sincerely,

Warner R. Broaddus
Vice President, General Counsel & Secretary

Charles S. Berkman
Associate General Counsel and
Chief Patent Counsel

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